Title: Radioactivity in Food Monitoring Review IA No: FOODSA0128 Lead department or agency: Food Standards Agency Other departments or agencies:	**Impact Assessment (IA)** Date: 10/12/2012 Stage: Consultation Source of intervention: Domestic Type of measure: Other Contact for enquiries: Christopher Thomas 020 7276 8728 radiation@foodstandards.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: RPC Opinion Status	

Cost of Preferred (or more likely) Option				
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, One-Out?	Measure qualifies as
£9.3m	£7.2m	-£0.77m	Yes	OUT

What is the problem under consideration? Why is government intervention necessary?

The Food Standards Agency (FSA) operates a programme to monitor for radioactivity in food. The results of this monitoring are used to assess the dose (risk) to consumers from eating this food.

The monitoring programme has run for several decades, with little significant change and should be reviewed to ensure it remains fit for purpose and that any future radiological monitoring programme has a clear rationale, is risk-based and in line with current best practice and guidance, ensures best value for money for the Government and reduces business burden.

What are the policy objectives and the intended effects?

The overall objective is to ensure a fit for purpose radiological monitoring programme for the future with a clear rationale supporting the following aims:

- Fulfil the UK's statutory requirements in relation to radioactivity in food
- Be risk-based and proportionate in line with current international radiological protection guidance
- Reassure consumers by assessing whether food produced in the UK has acceptably low levels of radioactivity
- Implement any future programme in a way that ensures value for money and reduces business burden.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

The following options have been considered:

- Option 1 - Do nothing (maintain the current monitoring programme) – The monitoring programme would continue in its current form.
- Option 2 - The FSA would stop all monitoring of radioactivity in food and associated reporting
- Option 3 - Sampling and analysis programme for food from England, Wales and Northern Ireland, carried out on a risk basis, in line with current internationally recognised best practice, and sufficient to meet UK Government commitments

Option 2 is not considered practical as the UK government would be in breach of European legal requirements and international agreements. Option 3 is the FSA's preferred option as it will provide a risk based approach to monitoring following international best practice and guidance.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: 03/2018						
Does implementation go beyond minimum EU requirements?				No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	MicroNo	< 20 No		SmallNo	Medium No	Large Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)				Traded:		Non-traded:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Chief Executive: [signature] Date: 11 December 2012

Summary: Analysis & Evidence

Policy Option 1

Description: 'Do Nothing' – Maintain current policy: the monitoring programme would continue in its current form

FULL ECONOMIC ASSESSMENT

Price Base Year 2012	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: **N/A**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	N/A		N/A	**N/A**

Description and scale of key monetised costs by 'main affected groups'

No incremental monetised costs are associated with policy option1: 'do nothing' as this is the baseline which all other options are appraised against. (Under the current programme, £1,784,457 per annum is recharged to the nuclear industry and a further £372,262 per annum is paid by the FSA. These costs would continue unchanged in Option 1.)

Other key non-monetised costs by 'main affected groups'

No incremental non-monetised costs are associated with this policy as this is the baseline which all other options are appraised against.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	N/A		N/A	**N/A**

Description and scale of key monetised benefits by 'main affected groups'

No incremental monetised benefits are associated with this policy option as this is the baseline which all other options are appraised against.

Other key non-monetised benefits by 'main affected groups'

No incremental non-monetised benefits are associated with this option as it is the baseline which all other options are appraised against.

Key assumptions/sensitivities/risks — Discount rate (%): N/A

There would be neither additional cost to industry nor benefit to consumers as this option will look to maintain the status quo.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: N/A	Benefits: N/A	Net: N/A	Yes	Zero net cost

Summary: Analysis & Evidence

Policy Option 2

Description: Cease the radiological monitoring programme

FULL ECONOMIC ASSESSMENT

Price Base Year 2012	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: **£18.2**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	£0		£0.04	**£0.35**

Description and scale of key monetised costs by 'main affected groups'

Ongoing cost to Governments of Crown Dependencies for the removal of the subsidy: £41,191 per annum (NPV of £354,559 over a period of ten years)

Other key non-monetised costs by 'main affected groups'

- The UK will be in breach of the Euratom Treaty and the Basic Safety Standards Directive which may lead to infraction proceedings.
- The UK will also be in breach of the OSPAR convention which may lead to loss of international reputation.
- There may also be additional costs to industry or EA if those parties decide to increase their own monitoring programme in response to the ceasing of the radiological monitoring programme

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	£0		£2.2	**£18.6**

Description and scale of key monetised benefits by 'main affected groups'

Ongoing benefits to nuclear sites which now will not be charged for the monitoring: £1,784,457 per annum (NPV of £15,360,046 over ten years)

Ongoing benefits to dairies which will now not be required to provide milk samples free of charge: £1,343 per annum (NPV of £11,560 over ten years)

Ongoing cost saving to FSA for non-site work which now will cease: £372,262 per annum (NPV of £3,204,315 over ten years)

Other key non-monetised benefits by 'main affected groups'

The FSA would reduce its total programme costs by the total amount of the current programme as represented by the monetised benefits above. These resource savings could be more appropriately redeployed in areas in which there may be a greater food safety risk

Key assumptions/sensitivities/risks — Discount rate (%): 3.5

The Channel Islands will continue to carry out monitoring if the monitoring subsidy they currently receive was removed

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £0.04	Benefits: £1.8	Net: -£1.7	Yes	OUT

Summary: Analysis & Evidence

Policy Option 3

Description: Optimised programme of radiological monitoring such that it is carried out on a risk basis

FULL ECONOMIC ASSESSMENT

Price Base Year 2012	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: **£9.3**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	£0		£0.06	£0.51

Description and scale of key monetised costs by 'main affected groups'

Ongoing cost to Governments of Crown Dependencies for the removal of the subsidy: £41,191 per annum (NPV of £354,559 over a period of ten years)
Ongoing cost to industry (one plant will be subject to increased costs): £5,130 per annum (NPV of £44,157 over ten years)
Ongoing cost to FSA: funding OSPAR requirements: £12,812 per annum (NPV of £110,232 over ten years)

Other key non-monetised costs by 'main affected groups'

None identified

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	£0		£1.1	£9.8

Description and scale of key monetised benefits by 'main affected groups'

Ongoing benefit to industry of an optimised programme: £883,047 per annum (NPV of £7,600,992 over ten years)
Ongoing benefit to FSA of an optimised programme: £252,615 per annum (NPV of £2,165,823 over ten years)

Other key non-monetised benefits by 'main affected groups'

FSA would reduce its programme costs, allowing it to redeploy resources in areas in which there may be a greater food safety risk

Key assumptions/sensitivities/risks — Discount rate (%): 3.5

The Channel Islands will continue to carry out monitoring if the monitoring subsidy they currently receive was removed

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £0.05	Benefits: £0.9	Net: -£0.84	Yes	OUT

Evidence Base (for summary sheets)

Problem under consideration

1. The Food Standards Agency (FSA) operates a programme to monitor for radioactivity in food. The results of this monitoring are used to assess the radiological dose to consumers, and hence the potential risk to consumers, from eating this food.
2. The FSA's programme is divided into:
   - monitoring around nuclear and other industrial sites or areas known to have high levels of radioactivity ('site monitoring'), and
   - monitoring at locations away from these sites.
3. The major components of the current programme are designed to sample and analyse a wide range of locally sourced foods that comprise local diets of people living around nuclear or industrial sites that release, or have in the past released, man-made radioactivity into the environment. The results are used to estimate annual retrospective doses to consumers to compare with EU annual dose limits, as required by the Basic Safety Standards (BSS) Directive[1]. However there are a number of components in the FSA's current programme that go beyond the requirements of the BSS Directive.
4. In terms of monitoring away from these sites, the programme samples milk and a range of foods that comprise general diets. This part of the programme serves to comply with requirements and recommendations under the Euratom Treaty[2] to annually report this data to the European Commission. Other samples are also taken around the UK's coast to comply with obligations under the OSPAR Convention[3].
5. A range of terrestrial and aquatic foods are also taken at locations away from nuclear sites (including the Channel Islands and Isle of Man) which go beyond the requirements of current legal and international obligations (as specified in paragraphs 3 and 4) and are therefore taken at the discretion of the FSA. Although there is no statutory obligation to do this, the data can be used as background data to compare against the results of data obtained from around nuclear sites. It also enables the FSA to compare any increases above the natural background radioactivity. However, analysis of these samples has either been unable to detect any activity, even with very sophisticated detection methods, or has shown very low levels of man-made radioactivity, well below any levels of concern. As the FSA now has many years of historic data, the value of adding further such data is limited. As this goes beyond the recommendations under the Euratom Treaty, it could be considered gold plating. Therefore the continuation of these aspects of the programme should be critically reviewed.
6. The scope of the FSA's current programme extends throughout England and Wales, the Channel Islands and the Isle of Man; it also includes milk from Northern Ireland dairies and aquatic sampling around the coastal waters of the British Isles. In Scotland, food and environment monitoring is combined and carried out by the Scottish Environment Protection Agency (SEPA) with advice from the FSA on the food aspects. Whilst the joint Scottish

[1] *Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.* OJ. 1996, 39(L159): 1 – 114.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1996L0029:20000513:EN:PDF

[2] The Euratom Treaty established the European Atomic Energy Community, whose member states are the same as the European Union, although it remains technically a legally distinct organisation. The Euratom Treaty helps to pool knowledge, infrastructure, and funding of nuclear energy. It ensures the security of atomic energy supply within the framework of a centralised monitoring system.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:084:0001:0112:EN:PDF

[3] The OSPAR Convention (originally **Os**lo and **Par**is Convention) is the current legal instrument guiding international cooperation on the protection of the marine environment of the North-East Atlantic. Work under the Convention is managed by the OSPAR Commission, made up of representatives of the Governments of 15 Contracting Parties and the European Commission, representing the European Union.
http://www.ospar.org

programme is out of scope of this review; SEPA and the FSA are liaising closely to ensure the same principles as laid out in this review are applied.

7. The results from the programme and the calculated potential doses to consumers are published annually in the Radioactivity in Food and the Environment (RIFE) Report[4]. The RIFE Report also includes radiological monitoring data from the Environment Agency (EA), SEPA and the Northern Ireland Environment Agency (NIEA), thereby providing a single comprehensive report on all government radiological monitoring data on food and the environment in the UK.
8. The costs of the radiological monitoring programmes undertaken around nuclear sites and the FSA staff time are recovered from the nuclear industry. The cost of the programme undertaken at locations away from nuclear sites is paid directly by the FSA and so is a cost to Government.

Rationale for intervention

9. The monitoring programme has run for several decades, with little change. The rationale behind the programme is overdue for review against the legal requirements and in order to consider, where samples are collected and analysed over and above the requirements, whether there is still a good consumer protection reason for continuing this work.

Policy objective

10. The overall objective is to ensure a fit for purpose radiological monitoring programme for the future with a clear rationale supporting the following aims:
    - Fulfil the UK's statutory requirements in relation to monitoring for radioactivity in food
    - Be risk-based and proportionate in line with current international radiological protection guidance
    - Reassure consumers by assessing whether food produced in the UK has acceptably low levels of radioactivity
    - Implement any future programme in a way that ensures value for money and reduces business burden.

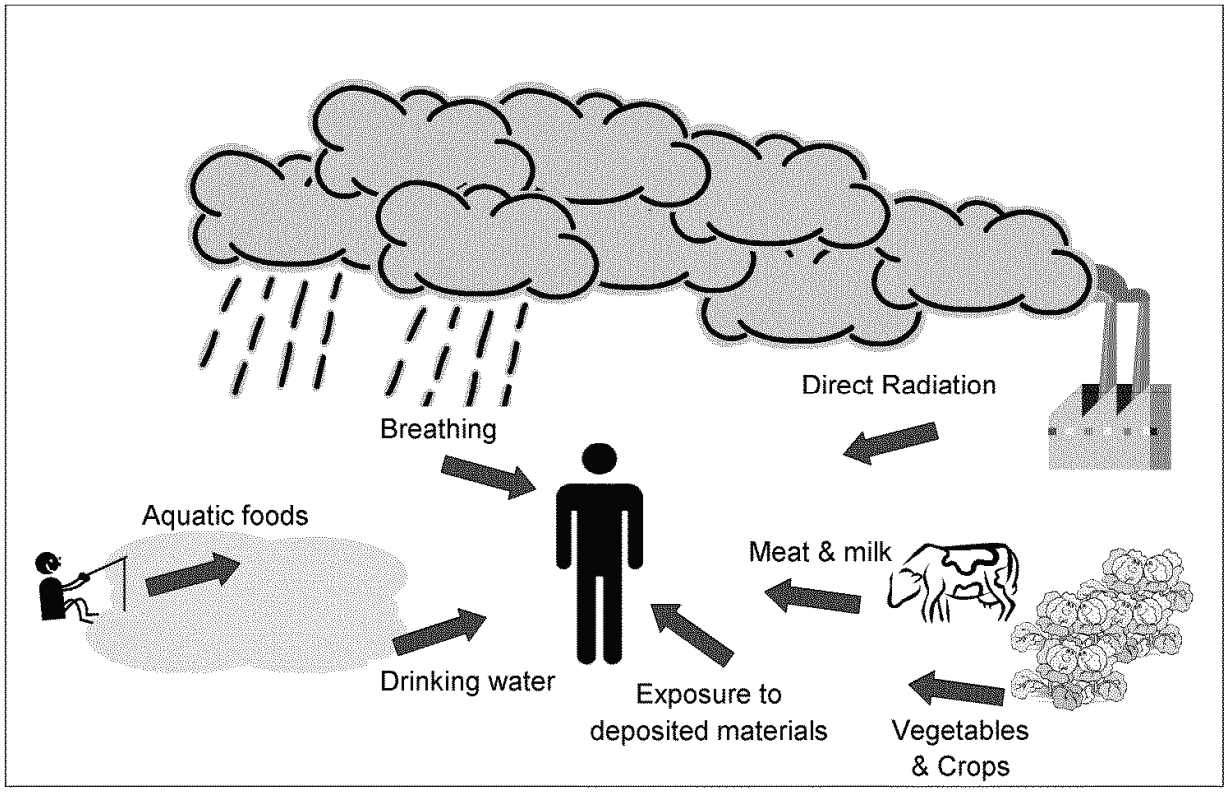
Background

Risks from radionuclides in food

11. In radiological protection, *effective dose* is a measure of the harmful effect of radiation to an exposed individual which takes account of the type of radiological contaminant, the age of the individual and the level of exposure (in this case, the quantity consumed as contamination within the food). Where individuals are continually exposed to a source of radioactivity for an extended period, the dose received over the duration of a year is often used and so doses are expressed in units of millisieverts per year (mSv/yr).
12. Consumers may be exposed to radioactivity from a number of sources, referred to as "pathways", see Figure 1.

[4] Environment Agency, Food Standards Agency, Northern Ireland Environment Agency and Scottish Environment Protection Agency. 2012. *Radioactivity in Food and the Environment, 2011*. http://www.food.gov.uk/science/research/surveillance/radiosurv/rife/

Figure 1 - Pathways for radiological exposure



13. Radiological protection is based on the principle that the risk of radioactive exposure is directly proportional to the dose received, in other words the greater the dose, the higher the risk of harmful effects (e.g. the risk of developing cancers). Radioactivity exists naturally in the environment and exposure to artificially produced radionuclides contributes a small proportion to this background dose. In the UK, the average dose to consumers from all sources of radiation is 2.7 mSv/yr, most of which is due to natural background radiation[5].
14. Exposure to natural radioactivity in the environment is largely unavoidable but it is possible to minimise the additional exposure received from man-made sources. Therefore, the European BSS Directive imposes a limit for members of the public exposed to artificially produced radiation from routine planned exposures (i.e. over and above that received from the natural background) of 1 mSv/yr.
15. In order to assess the risk to consumers, it is important to consider all sources of man-made exposure a consumer receives as a combination from all these pathways, not just the food pathway in isolation. Therefore, data on radioactivity in food is combined with data on other sources of exposure to provide a "*total dose*" from all man-made sources. In 2011, the highest total dose for members of the public from planned artificial exposures in the UK was approximately a quarter of the limit at 0.22 mSv/yr [6].
16. The FSA's monitoring programme collects and analyses samples to measure the levels of man-made radionuclides in food for use in calculating the total dose that consumers receive from artificial radioactivity.

[5] Health Protection agency website: http://www.hpa.org.uk/Topics/Radiation/UnderstandingRadiation/UnderstandingRadiationTopics/DoseComparisonsForIonisingRadiation/

[6] Environment Agency, Food Standards Agency, Northern Ireland Environment Agency and Scottish Environment Protection Agency. 2012. *Radioactivity in Food and the Environment, 2011*. http://www.food.gov.uk/science/research/surveillance/radiosurv/rife/

Legal requirements

17. The purpose of the majority of the samples collected under the FSA's radiological monitoring programme is to contribute to the UK's requirements under the Basic Safety Standards (BSS) Directive[7]. This EU Directive requires the Competent Authority to assess the total retrospective dose to members of the public, from all sources of man-made radioactivity via all possible pathways of exposure. In the UK, this role is carried out by the environment agencies: the EA for England and Wales; the SEPA for Scotland; and the NIEA for Northern Ireland.

18. The Environmental Permitting Regulations 2010 (EPR10) [8] implement the BSS Directive in England and Wales with respect to authorising and monitoring radioactive releases into the environment. In Scotland, this is implemented by the Radioactive Substances Act 1993 (RSA93)[9]. EPR10 and RSA93 give EA and SEPA respectively the power to recharge industry for regulatory work associated with Permits or Authorisations. The power to recharge also extends to the work carried out by other organisations such as the FSA.

19. The concentration data for food is an essential part of the total dose calculation, and the FSA supplies this data to the EA for England and Wales. In Scotland, SEPA carry out the food monitoring on behalf of the FSA in Scotland, and there are no nuclear sites in Northern Ireland, so the same level of monitoring is not required. Without data on food the EA would not be able to appropriately discharge their statutory duties and the FSA has a commitment to supply this through a Working Together Agreement under EPR10.

20. In addition, the programme fulfils a number of other requirements. Samples of milk and mixed diet are collected to comply with the Euratom Treaty, particularly Articles 35 and 36[10], as set out in European Commission Recommendation 2000/473[11], which require all EU Member States to monitor and report the levels of radioactivity in a number of environmental samples. The FSA gathers data on food for England, Wales and Northern Ireland and reports the results to the Joint Research Centre (JRC) of the European Commission (EC) (SEPA gathers the equivalent data for Scotland).

21. Data from the aquatic part of the monitoring programme is used to assess progress against the 'UK Strategy for Radioactive Discharges'[12]. One of the objectives of this strategy is compliance with the Radioactive Substances Strategy of the OSPAR Convention[13], to which the UK is a signatory. The Radioactive Substances Strategy has the objective of reducing radioactive pollution into the North Atlantic, such that concentrations in the environment are near background levels for naturally occurring radioactive substances and close to zero for artificial radioactive substances by 2020.

22. Further details on the legal and convention requirements regarding radioactivity in food and the environment can be found in Section 3.1 of Appendix 1 to the RIFE Report[14].

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[7] *Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.* OJ. 1996, 39(L159): 1 – 114. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1996L0029:20000513:EN:PDF

[8] The Environmental Permitting (England and Wales) Regulations, 2010 (SI 2010 No. 675) http://www.legislation.gov.uk/uksi/2010/675/contents/made

[9] The Radioactive Substances Act 1993 (1992 c. 12) http://www.legislation.gov.uk/ukpga/1993/12/contents

[10] Consolidated Version of the Treaty Establishing the European Atomic Energy Community (2010/C 84/01) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:084:0001:0112:EN:PDF

[11] Commission Recommendation on the application of Article 36 of the Euratom Treaty concerning the monitoring of the concentrations of radioactivity in the environment for the purpose of assessing the exposure of the population as a whole. OJ. 27 July 2000, 2000/473/Euratom. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:191:0037:0046:EN:PDF

[12] Department of Energy and Climate Change, Department of the Environment, Northern Ireland, The Scottish Government and Welsh Assembly Government. 2009. *UK Strategy for Radioactive Discharges*. http://www.decc.gov.uk/assets/decc/what%20we%20do/uk%20energy%20supply/energy%20mix/nuclear/radioactivity/1_20090722135916_e_@@_dischargesstrategy.pdf

[13] *Convention for the protection of the marine environment of the North-East Atlantic.* OSPAR, 2000. http://www.ospar.org

[14] Environment Agency, Food Standards Agency, Northern Ireland Environment Agency and Scottish Environment Protection Agency. 2012. *Radioactivity in Food and the Environment, 2011*. http://www.food.gov.uk/science/research/surveillance/radiosurv/rife/

Nuclear sites

Figure 2 – Map of UK nuclear sites[15]*:*

23. Nuclear sites must hold a nuclear site licence for their operations, and must comply with conditions that are attached to the licence. Nuclear installations include nuclear power stations, nuclear fuel manufacturing facilities, fuel reprocessing, facilities for research, radiochemical production and facilities for the storage of bulk quantities of radioactive material which has been produced or irradiated in the course of the production or use of nuclear fuel. A full list of the nuclear licensed sites in England, Wales and Scotland (there are none in Northern Ireland) can be found on Health and Safety Executive's website at http://www.hse.gov.uk/nuclear/regulated-sites.htm

24. It is common for nuclear sites to be located together, for example many second generation nuclear power stations were built on sites adjacent to existing first generation sites. These adjacent sites will share a boundary but are often run by different operators under separate site licences and so are regulated separately. However, due to their close proximity they are treated as a single site for regulatory monitoring and retrospective total dose assessments.

[15] Environment Agency, Food Standards Agency, Northern Ireland Environment Agency and Scottish Environment Protection Agency. 2012. *Radioactivity in Food and the Environment, 2011*. http://www.food.gov.uk/science/research/surveillance/radiosurv/rife/

The recharge cost for monitoring at these adjacent sites is split between the operators either equally or by an agreed ratio depending on the relative discharges of the respective sites.

25. It should be noted that nuclear sites may be owned by one organisation and operated by another: it is the 'operator' that holds the site licence. A number of the sites are in the process of 'decommissioning', many are first generation nuclear power stations which have shut down or old research facilities.

26. The majority of nuclear sites are owned by the Nuclear Decommissioning Authority (NDA), which is a non-departmental public body formed under the Energy Act 2004, with responsibility for:

    - decommissioning and cleaning up civil nuclear facilities ensuring that all the waste products, both radioactive and non-radioactive, are safely managed
    - implementing Government policy on the long-term management of nuclear waste
    - developing UK-wide nuclear Low Level Waste (LLW) strategy and plans
    - scrutinising decommissioning plans of British Energy

27. The NDA owns all decommissioning sites, plus the majority of the sites that manufacture or reprocess nuclear fuels and also the UK's Low Level Waste Repository. However, whilst these sites are owned by the NDA, they do not directly manage the facilities but contract out the delivery of site programmes through management and operation contracts with licensed operators, Site Licence Companies, at each site.

28. In addition, there are a number of defence sites, owned and operated by the Ministry of Defence (MoD). The MoD internal regulator, the Defence Nuclear Safety Regulator (DNSR) leads on regulating nuclear safety at these sites. It is MoD policy to ensure, where reasonably practicable, that standards on defence related nuclear sites are at least as good as those required by civil regulation[16]. The FSA's monitoring programme and the RIFE Report include these defence sites and they are included in the scope of this review.

29. There is, therefore, a mixture of public and private organisations involved in the UK's nuclear industry. However, for the purpose of recharging, costs are levied on the site operator which in most cases is a private business and so for the purposes of this Impact Assessment all recharge costs have been considered together under the heading of 'nuclear sites'.

30. The following of the FSA's current work is recharged to the nuclear sites:

    - Prospective dose assessments as part of the permitting process (including supporting work for this, e.g. Habits surveys[17]);
    - Monitoring programme, including sampling, analysis and management;
    - The RIFE Report. This includes data analysis to produce a retrospective dose assessment for the year of the report, as well as drafting and production costs of the report itself.

31. Work covered by the first bullet point (prospective dose assessments) is required so that the FSA can provide the necessary advice to the EA to enable them to fully assess applications to discharge radioactivity under EPR10. **This work has been reviewed internally by the FSA and will continue; none of the options proposed in this review will alter the actions and subsequent recharges based on this aspect of the programme.**

[16] http://www.hse.gov.uk/nuclear/defence.htm

[17] Habit surveys give site specific information on diets and occupancy habits of people near nuclear sites. This data identifies the foods consumed and activities undertaken by members of the public which expose them to radioactive contamination and is used in the assessment of radiological dose.

32. **This review and impact assessment considers the impact from changes to the second and third bullet points above.** However prospective dose assessment procedures are outlined below since it is the FSA's means to ensure food safety and therefore is associated with any minimising risks outlined in this impact assessment. Aspects of the prospective assessments programme (e.g. habits surveys) are also used in the monitoring programme under consideration in this impact assessment.

Prospective dose assessments for permits

33. A nuclear site needs a permit to release radioactive waste into the environment. Before an operator of a nuclear site may start operations, or change them if they have already started, they must receive permission from the relevant environment agency. The EA manages applications for these Permits in England and Wales under EPR10, and SEPA manage applications for the equivalent, termed Authorisations, in Scotland under RSA93. There are currently no nuclear sites in Northern Ireland.
34. These Permits or Authorisations set out limits for the amount and type of radioactive substances that may be released into the environment. The environment agencies consult the FSA on the food safety implications of any applications they receive.
35. The risk from radioactivity in food is assessed by calculating the radioactive dose received by consuming that food (see Annex I for further details). The FSA carries out a prospective dose assessment before the Permit or Authorisation is granted. This prospective assessment ensures that discharge limits are applied which keep the levels of radioactivity which the site is allowed to release far below any levels which would affect the safety of food. As these prospective assessments are carried out before radioactivity is released they are considered a protective measure.
36. Prospective assessments assume that releases into the environment are at the limit the site is applying for and that food will be produced where levels of radioactivity released from the site are going to be at their highest (this approach is used for both terrestrial and aquatic foods). These assumptions are precautionary being designed for protective principles. The prospective assessment calculates whether a consumer eating large quantities of food produced in these most affected areas will exceed the acceptable dose (currently a maximum of 30% of the annual dose limit of 1 mSv/yr). If the dose to this most affected consumer is acceptable, and by implication the dose to other consumers will be lower still, then the releases of radioactivity from the site is considered to be acceptable and will not lead to concerns over the safety of food.
37. These prospective assessments are the FSA’s primary means of ensuring food is safe from radioactive waste released into the environment. All FSA staff costs and associated underpinning development costs for assessment work are recharged to the nuclear sites.

Food monitoring – Verification of dose estimates through retrospective dose assessments

38. The FSA’s monitoring programme produces data on the levels of radioactivity in a range of foods, primarily those produced near nuclear sites. These data are used to calculate the radiological dose received from actually consuming these foods and the dose is used to assess risk to human health. However, these ‘retrospective’ dose assessments do not prevent consumers receiving doses, as the assessment is carried out a significant time after the consumers are exposed to these radioactive releases. Therefore, it is not a preventative measure, but forms a method of checking that the operations of the nuclear sites have not been unduly detrimental to human health and the environment. The retrospective assessments from monitoring data are also used to verify the accuracy of prospective assessments carried out during the permitting process (see previous section). As such, the

monitoring programme is there to support, rather than lead, the protection of consumers from radioactivity.

39. Results from the FSA's monitoring programme are combined with environmental data collected by EA, SEPA and the NIEA and published in the annual report on Radioactivity in Food and the Environment, the 'RIFE' Report.

40. The RIFE Report has been an effective method of ensuring open and transparent publication of the FSA's data and puts this into context by presenting it alongside the data of the environment agencies to give a complete picture of the public's exposure to radioactivity in the UK. These reports continue to show that consumers' exposure to artificially produced radioactivity via the food chain (for aquatic, terrestrial and total dose pathways) remain well below the EU annual dose limit for members of the public of 1 mSv/yr for all artificial sources of radiation and therefore demonstrates the UK's compliance with the BSS Directive on public exposure to radiation.

41. Further details on how dose assessments which are carried out are included in Annex I.

42. Long term trends also show that concentrations of radionuclides in food and the environment over the past two decades have shown large and sustained reductions in the majority of cases[18].

Consumer reassurance

43. The prospective assessments, as part of the permitting procedure, are used to ensure permitted radioactive discharges remain significantly below any levels which could cause food safety issues. The monitoring programme does not itself protect the safety of food as results are only available sometime after the food will have been consumed and so it can only assess the dose that consumers have already received. However, the monitoring programme can provide the reassurance to consumers where it shows that releases of radioactivity into the environment are indeed below levels which would be a food safety concern.

Outline of current radiological monitoring programme

Outline of programme

44. The scope of the FSA's radiological monitoring programme extends throughout England, Wales and Northern Ireland; it also includes the Channel Islands, the Isle of Man and the coastal waters of the British Isles and further afield. In Scotland, SEPA carries out both food and environmental monitoring for radioactivity, working closely with the FSA on its food programme.

45. The FSA's radiological food monitoring programme is currently split into the 'Aquatic Monitoring Programme', which has been going, in one form or another, since 1957; and the 'Terrestrial Monitoring Programme', in operation since 1986. Sampling and analysis of foods and some environmental indicators are carried out in order to find the levels of radioactivity, which are used for calculations of retrospective dose estimates to consumers.

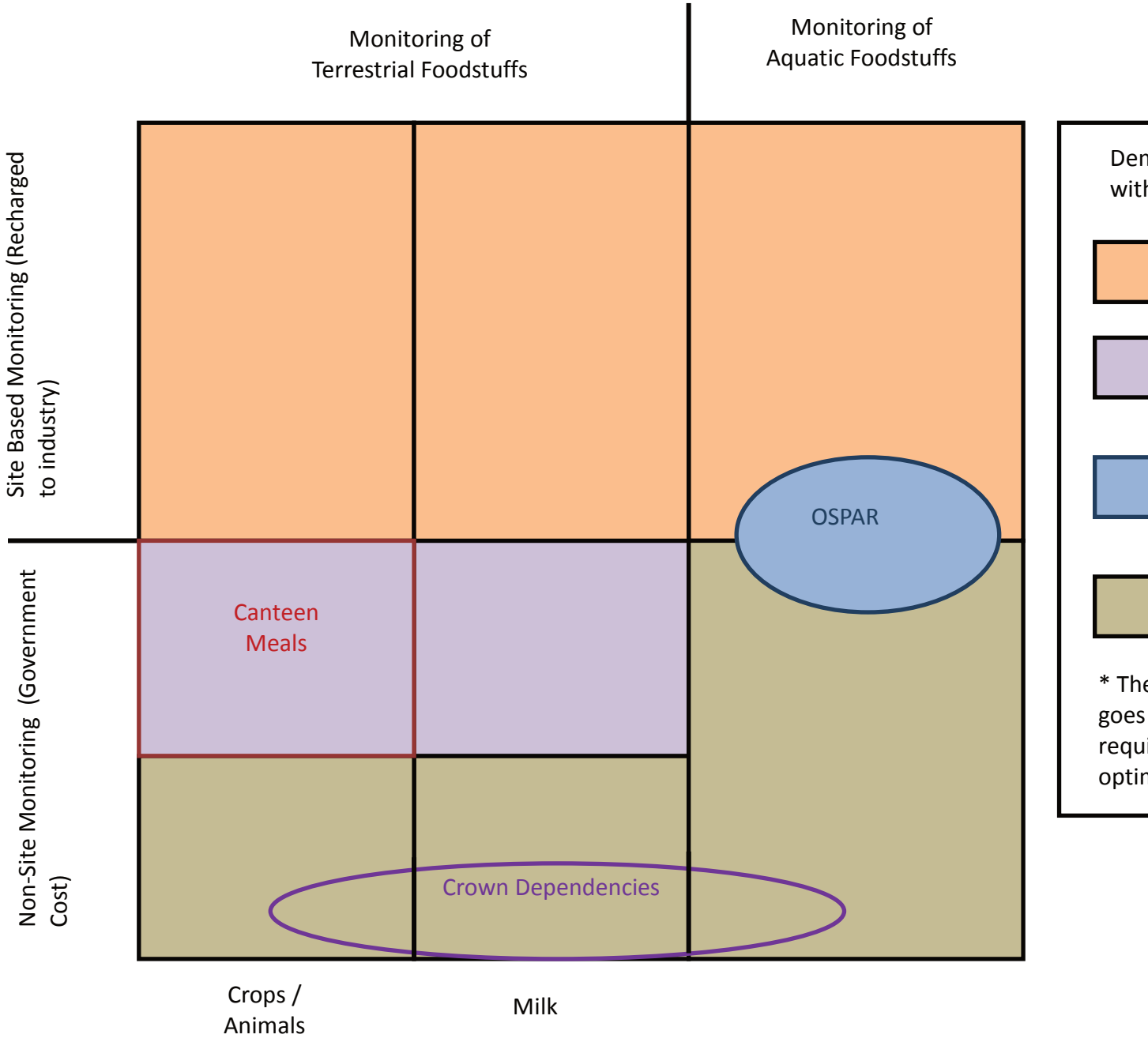
46. Monitoring is carried out around nuclear sites and other locations known to have potentially elevated levels of radioactivity in England and Wales. Samples are collected of locally sourced foods (including milk, meat, cereals, fruit, vegetables, fish, crustaceans and molluscs). The samples are analysed for a range of different radionuclides depending on which radionuclides the site is allowed to release into the environment. The costs of the site-

[18] Environment Agency, Food Standards Agency, Northern Ireland Environment Agency and Scottish Environment Protection Agency. 2010 . *Summary of Radioactivity in Food and the Environment 2004-2008*.
http://www.food.gov.uk/science/research/surveillance/radiosurv/rife/rife5yr

specific monitoring work and the associated FSA staff time are recovered from the nuclear sites through the EA's cost recovery scheme under EPR10[19].

47. Food samples are also taken away from nuclear sites and are predominantly funded by the FSA. These samples serve a variety of purposes, including satisfying obligations under the Euratom Treaty and the OSPAR Convention. However, some of these samples are beyond the requirements of current legal and international obligations and are therefore taken at the discretion of the FSA.

Figure 3 – Indicative diagram showing the legislation or international obligations covering each aspect of the radioactivity in food monitoring programme.



NB: This diagram is intended to be indicative and the relative sizes of each area does not represent the relative size of the programme components

[19]The EA sets out the principles for recharging on their website: http://www.environment-agency.gov.uk/business/regulation/38823.aspx

48. The programme has the flexibility to include additional samples or further analysis on routine samples if intelligence is received of a possible food safety concern. A particular example of this was when the FSA's programme detected elevated levels of tritium (H-3) in samples in the vicinity of a nuclear site. After carrying out a risk analysis to ensure there was no food safety concern, the results were used to modify the regulation regarding that site. This led to a change of equipment by the site operators and in turn resulted in a reduction in tritium discharges from that site.

49. Results from the FSA's radiological monitoring programme have shown that the risk to consumers from radioactivity in food has been consistently low for many years, and the regulatory system is such that this is likely to continue. Additionally, in recent years there have been decreases in radioactive discharges by the nuclear sites, and reductions in levels of radioactivity in food and the environment have been seen. The analysis of many samples has either been unable to detect any activity, even with very sophisticated detection methods, or has shown very low levels of man-made radioactivity, well below any levels of concern. Therefore, there is limited justification in maintaining aspects of the programme beyond that required for compliance with legal and international obligations.

Components within the programme

Aquatic monitoring

50. Samples are taken of fish, shellfish (including molluscs and crustaceans), edible seaweeds and some environmental indicators (usually seaweed) along coastal areas, in estuaries and certain inland rivers and lakes. Samples are selected on the basis of consumption data and how likely the species is to take up radioactivity.

51. Samples are either collected by FSA contractors from known locations or purchased from suppliers who can provide details of the sample origin.

Terrestrial monitoring

52. Samples of crops, milk and animals (including game birds and poultry) are taken in the vicinity of nuclear sites in England and Wales. Milk is a useful food to sample as it is consumed in relatively large quantities, so is often the biggest contributor to dose, and cows graze a wide area, so it is a good representation of radioactivity deposited on farmland from releases into the atmosphere. Milk is produced throughout the year, widespread across much of the country, and radioactivity passes relatively quickly from the environment into milk (within a few days).

53. Milk samples are also taken across England, Wales and Northern Ireland remote from nuclear sites which are used for compliance with the Euratom Treaty. A small number of complete meals are taken from canteens across the UK to represent 'mixed diet' samples and these are also reported to the EU for compliance with the Euratom Treaty.

54. Further samples of crops and a small number of animals are taken away from nuclear sites to build up a broader picture of the UK as a whole, rather than focusing exclusively around nuclear sites. In some cases, where it is not possible to get a crop sample, then an indicator sample may be taken instead (grass, silage or soil).

55. Samples are either collected by FSA contractors from known locations or purchased from suppliers who can provide details of the sample origin.

Radioactivity in Food and the Environment (RIFE) Report

56. Both the analytical results and the retrospective doses to consumers calculated from the monitoring data are published annually in the Radioactivity in Food and the Environment (RIFE) Report. The RIFE Report also includes environmental radiological monitoring data from the EA, SEPA and the NIEA, thereby providing a comprehensive report on government

radiological monitoring data on food and the environment in the UK. The FSA is currently the lead partner in this project and holds and manages the contract for its production. Both the contractual costs and FSA staff costs associated with management of the RIFE Report are recharged to the nuclear sites.

57. The options considered in this Impact Assessment are presented in paragraph 60 onwards. Under Options 1 and 3 it is proposed that the FSA continues to lead the RIFE Report partnership as the FSA would remain the major contributor and this arrangement currently works well for all four partner organisations. This would mean the continuation of a co-ordinated publication for radiological monitoring in food and the environment across the UK. Under Option 2, the FSA would no longer be part of the RIFE Report partnership, nor submit data to be included in the report.

Guidance on design of radiological monitoring programmes

58. Limited guidance is provided by the European Commission on the detailed requirements for compliance with the BSS Directive and Articles 35/36 of the Euratom Treaty. In the absence of clear guidance, the FSA and environment agencies in the UK have looked at internationally accepted best practice from the International Atomic Energy Agency (IAEA)[20].

59. In 2005, the IAEA issued guidance of best practice on what regulators and operators monitoring programmes could look like and how they might be composed[21]. In 2010, 'Technical Guidance Note 2'[22] was published jointly by the EA, SEPA and the FSA in order to provide the UK interpretation of the IAEA guidance. It was developed by the Radiological Monitoring Standards Working Group (RMSWG), made up of representatives from the EA, SEPA, Nuclear Decommissioning Authority, FSA, nuclear industry and experts. The RMSWG is a sub-group of the Nuclear Industry Liaison Group[23].

Options

Summary

60. Three options have been considered in this impact assessment:

- **Option 1 – Do nothing (maintain the current monitoring programme)**
  The monitoring programme would continue in its current form. UK Government and nuclear sites would continue to benefit from a comprehensive data set, including meeting all legal requirements and providing consumer reassurance. However, for the level of consumer risk the programme is expensive in comparison with other contaminants in food. In addition, this option would miss the opportunity to bring the programme in line with current international best practice and guidance and would not address the current gold-plating of European requirements.
- **Option 2 – FSA ceases radiological monitoring in food, and associated reporting**
  The FSA would stop all monitoring of radioactivity in food and associated reporting. This option would deliver significant cost savings to both nuclear sites and government. However, the UK Government would be in breach of several legislative requirements and

[20] The IAEA is an international agency within the United Nations family which works with its Member States and multiple partners worldwide to promote safe, secure and peaceful nuclear technologies.

[21] IAEA Safety Standards Series No. RS G-1.8. Environmental and Source Monitoring for Purposes of Radiation Protection. Safety Guide. IAEA, Vienna, 2005. http://www-pub.iaea.org/MTCD/publications/PDF/Pub1216_web.pdf

[22] Environmental Radiological Monitoring: Environment Agency, Food Standards Agency & Scottish Environment Protection Agency, 2010. *Radiological Monitoring Technical Guidance Note 2.* http://publications.environment-agency.gov.uk/PDF/GEHO0811BTVY-E-E.pdf

[23] The Nuclear Industry Liaison Group meets three times a year to provide a forum for discussion between nuclear site operators and the UK environment agencies. A number of other organisations, including the Nuclear Installations Inspectorate, Nuclear Decommissioning Authority and Food Standards Agency, also attend.

international agreements. This would lead to the possibility of infraction proceedings against the UK and severe reputational risks to the FSA and by extension, the UK Government as a whole. There would also be a risk of not having the data necessary to detect a radiation food safety problem, and reduced capability of the FSA to respond to a food safety incident involving radioactive contamination. For these reasons, Option 2 is not considered feasible.

- **Option 3 – Optimised monitoring programme**
  The FSA would continue a programme of monitoring radioactivity in food, but the programme would be re-designed to reduce costs to government and industry. Sampling and analysis for food samples from England, Wales and Northern Ireland, would be carried out on a risk basis, in line with current internationally recognised best practice and sufficient to continue to meet UK Government commitments. The optimised programme would achieve the key benefits and provide better value for money than the current programme. Option 3 is therefore the FSA's preferred option.

61. A range of alternative options were considered as part of the FSA's review but were subsequently discounted as they did not meet the key aims and objectives of this review. Further details can be found at Annex III.

Table 1: Summary of components of the programme to be maintained under each option

		Option 1	Option 2	Option 3
Prospective assessments	Assessment of applications for Permits or Authorisations to release radioactivity into the environment (BSS Directive)	✓	✓	✓
Habit surveys	Gathering site specific information on diets and occupancy habits of people near nuclear sites (BSS Directive)	✓	✓	✓
Aquatic (fish / shellfish) monitoring	Site monitoring (BSS Directive)	✓		✓*
	OSPAR Convention	✓		✓*
	Non-site monitoring	✓		
Terrestrial (crops / animal) monitoring	Site monitoring (BSS Directive)	✓		✓*
	Non-site monitoring	✓		
Terrestrial milk monitoring	Site monitoring (BSS Directive)	✓		✓*
	Non-site dairies (Euratom Art. 35/36)	✓		✓
	Other non-site monitoring	✓		
Indicator monitoring	Soil/Grass/Silage	✓		
Mixed diet monitoring	Canteen Meals (Euratom Art. 35/36)	✓		✓

** These aspects of the programme will continue under Option 3 but will be optimised.*

Description of options

Option 1 – Do nothing (maintain current policy)

62. The FSA's radiological monitoring programme would continue in its current form. It would take food samples around the nuclear sites in England and Wales and away from these sites, which also includes samples from Northern Ireland, the Isle of Man and the Channel

Islands. Samples required to demonstrate compliance against the OSPAR Convention would be retained (although it should be noted that all OSPAR samples are currently taken near nuclear sites as part of the site monitoring programme, and are recharged to nuclear sites, so serve a dual purpose and are not currently an additional cost to Government).

63. A summary table of total sample numbers is provided in Table 2 below. Details of numbers and types of samples taken at each individual site are published in the RIFE Report.

Table 2: Total sample numbers in current programme and under Option 1

		Site related	*Non-site related*
Aquatic	Fish	161	82
	Crustaceans & Molluscs	294	33
	Aquatic Vegetables	20	0
	Seaweed	67	0
Terrestrial	Milk	2186 (91 farms)	267 (26 dairies)
	Meat and meat products	21	5
	Poultry and eggs	3	0
	Fruit and vegetables	128	41
	Cereals	17	0
	Game	10	0
Indicators	Soil/Grass/Silage	55	0
Mixed Diet	Canteen Meals	N/A	20 (11 canteens)

Option 2 – FSA ceases radiological monitoring in food, and associated reporting

64. Under this option, the FSA would cease its entire radiological monitoring programme, the main benefit of which would be saving the total cost of the programme, both contractual costs and FSA staff resources, to both Government and industry. However, the numerous disadvantages, as laid out under risks and wider impacts, mean that this option is not considered practical.

65. The FSA's strategic objective is "safer food for the nation"[24]. However, the primary purpose of the radiological monitoring programme is not, strictly speaking, to ensure food safety, but the results contribute to the overall assessment of regulatory compliance, required under the Basic Safety Standards Directive and Euratom Treaty. Stopping the current programme would be a low risk in terms of food safety; the FSA would maintain its input into the 'permitting' process, ensuring that radioactive discharges by nuclear sites have limits set upon them so that levels of radioactivity in food would be well below levels which could be a food safety concern. The EA routinely monitors discharges from nuclear sites and this data is and can be used to ensure that operational discharges are kept within these permitted levels.

[24] Food Standards Agency's Strategy to 2015 http://www.food.gov.uk/about-us/publications/busreps/strategicplan/

66. The FSA would no longer be part of the RIFE Report partnership, nor submit data to be included in the report. The FSA would have a minimal role in the project, commenting on a final draft of any document(s) produced by the other partners, in line with other Government organisations.

Option 3 – Optimised monitoring programme

67. Under this option, the FSA would continue to sample food as required to meet the UK Government's international and regulatory commitments, but the programme would be optimised using current guidelines, principally the Radiological Monitoring Technical Guidance Note 2.

68. The monitoring of radioactivity in food samples by a Government organisation is required to fulfil the UK's three statutory obligations in this area:

    - to produce (and report) retrospective dose assessments for the BSS Directive;
    - to report data for compliance with Article 35/36 of the Euratom Treaty; and
    - to monitor the status of the marine environment for the OSPAR Convention.

69. There is a general expectation within other government departments and agencies that the FSA should have a lead role for any UK Government food sampling.

70. Basing the need for the programme on these three obligations will give clear objectives for the programme, which will also have a clear, risk-based rationale for sampling plan design, based on the most up-to-date internationally agreed best practice.

71. The primary objective of an optimised monitoring programme would be to supply the necessary data on radioactivity in food samples to the EA, to allow calculation of retrospective total dose assessments. This means the UK Government can ensure that doses are within EU annual dose limits, thereby meeting BSS Directive requirements.

72. The radionuclides analysed would be based on those released into the environment from each site (including historical discharges where appropriate), and previous results of food monitoring would be taken into account. This means that both the sampling and analysis would effectively be proportional to the risk from each site, and therefore can be considered a risk-based approach to programme design.

73. The FSA would split sites into three tiers depending on the level of risk (see Annex II for further details). Where sites are transferring from active operation, like power generation, into the early stages of decommissioning, the tiered approach will allow for a more flexible programme to be introduced, with sites moving between tiers when trigger levels are reached. This would build on the current annual reviews where small incremental changes have always been made. This flexibility can work for potential increased requirements as well as if the new nuclear build programme required it. However, the majority of sites who will enter the decommissioning stage in the next ten years are already in the lower tier proposed and it is unlikely new nuclear facilities will begin full operation within the next ten years due to planning and construction time-lines. Therefore, for the purposes of this Impact Assessment, it has been assumed that no sites will change tier over the next ten years.

74. For the purpose of this Impact Assessment it has been assumed that the FSA would continue to manage the site related monitoring with costs recharged to site operators. Monitoring under this option could be transferred directly to the site operators to collect and analyse the required samples with the data reported to the FSA. However, as costs are already recharged to industry, there would be no substantial changes in the costs and benefits presented whether the monitoring is carried out by the FSA or transferred to site operators. This alternative option has been discounted due to the additional burden on industry of reporting data, lack of independent verification and the loss of capability within

the FSA to respond to nuclear incidents (see Annex III). However, we would welcome views on whether the FSA should maintain an independent programme which is recharged or whether the sample collection and analysis could be transferred to site operators.

75. The secondary objective would be to obtain food samples required as part of the data that is required by the UK to satisfy its international obligations as regards radiological monitoring (Euratom Treaty and OSPAR Convention).

76. For the Euratom Treaty, samples would be taken of milk and mixed diet in England, Wales and Northern Ireland, similar to the present programme, and reported to the JRC of the EC. However, the sampling and analysis schedules for these projects would be optimised to ensure they are focused on satisfying Euratom Treaty requirements using Commission Recommendation 2000/473/Euratom.

77. The programme would also include samples of fish and molluscs to satisfy obligations for the OSPAR Convention, although the sampling schedule would be optimised to ensure it is in line with current OSPAR commitments and guidance[25]. Although the OSPAR Commission uses the data from these samples to monitor the state of the marine environment (and not for food safety or for dose assessments), the FSA is well placed to take them on behalf of the UK Government as the data is also used for dose calculations as part of the site programme, and therefore serve a dual purpose. The majority of samples required for OSPAR monitoring can be selected from those in the proposed site monitoring programme with only a few extra analyses and therefore this multiple use of the same samples represents good value for money for UK Government. Only four additional samples will be required but these can be efficiently collected alongside the site samples with minimal additional cost to Government.

78. All other components of the current monitoring programme would cease. This would include all terrestrial crop, animal and aquatic samples taken away from nuclear sites (for general surveillance purposes), other than those required for the Euratom Treaty Article 35/36 submission. Subsidies for analyses of samples taken by the Governments of Jersey, Guernsey and the Isle of Man would also cease.

79. A summary table of total sample numbers proposed under this option is provided in Table 3 below. A detailed explanation of the criteria for each tier and the structure of this tiered approach is provided in Annex II.

Table 3: Total sample numbers in proposed programme under Option3

		Site related	Non-site related
Aquatic	Fish	45	0 *
	Crustaceans & Molluscs	53	4 *
	Aquatic Vegetables	5	0
	Seaweed	0	0
Terrestrial	Milk	619 (47 farms)	246 (23 dairies)
	Meat and meat products	16	0
	Poultry and eggs	2	0
	Fruit and vegetables	29	0
	Cereals	24	0
	Game	10	0
Indicators	Soil/Grass/Silage	0	0
Mixed Diet	Canteen Meals	N/A	20 (11 canteens)

[25] Agreement on a Monitoring Programme for Concentrations of Radioactive Substances in the Marine Environment (Update 2011).OSPAR, 2011. Agreement 2005-08. 1.
http://www.ospar.org/documents/dbase/decrecs/agreements/05-08_monitoring%20radioactive%20substances.doc

** The majority of OSPAR samples would be collected under the site related monitoring and used in addition to show compliance with the OSPAR Convention. In total, 9 fish and 27 molluscs will be used to submit data under the OSPAR Convention.*

80. It is proposed that the FSA continues to lead the RIFE Report partnership as the FSA would remain the major contributor and this arrangement currently works well for all four partner organisations. This would mean the continuation of a co-ordinated publication for radiological monitoring in food and the environment across the UK.

Cost and benefits

Option 1 – Do nothing (maintain the current monitoring programme)

There are no incremental monetised costs and benefits associated with policy Option 1: 'Do nothing', as this is the baseline which all other options are appraised against.

Risks

81. The current programme no longer has a clear basis for sample selection. This means that the scale and cost of the programme charged to nuclear sites may not be in proportion to the requirements for a programme and could be open to challenge by the nuclear industry. A lack of rationale behind sample selection also means that the cost to Government is higher than is needed to meet current requirements. Some parts of the programme have been continued 'just in case', but they do not contribute to the demonstration of regulatory compliance and the risk they are assessing is very low.

Wider impacts

82. UK Government will be able to continue to show that retrospective doses are within EU annual dose limits, thereby meeting BSS Directive requirements. Results are also used to meet the UK's obligations under the Euratom Treaty and OSPAR Convention. In regards to OSPAR samples, if the sampling plan remains unchanged, this would mean consistency in the data and enable comparisons between historical and future data, which is important as the focus of OSPAR is on trend analysis.

83. The programme provides a comprehensive data set, which means that the UK picture of contamination is well understood. In the past, information from the programme has been used to support policy development, e.g. setting of Codex Alimentarius standards[26] and also in international discussions. For instance, data collected on the radioactive contaminant Technetium-99m in lobsters was used as defence when the Irish Government undertook legal proceedings against the UK regarding discharges from the Sellafield nuclear site.

84. The programme provides independent data that nuclear sites can point to, to reassure government and the public that their operations are within agreed limits. From discussions with the nuclear site operators the FSA understands that they see a benefit to an independent monitoring programme providing consumer reassurance.

85. This programme would help to maintain capability and expertise of UK labs to process large numbers of radiological samples. This would be a benefit to the UK's resilience in the event of a radiological incident or emergency where a large number of samples may need to be analysed within a short period of time.

86. However, the existing monitoring programme is large, costing approximately £1,900,000 per year with £1,510,000 recharged to the nuclear industry and £370,000 funded by

[26] The Codex Alimentarius Commission, established by FAO and WHO in 1963 develops harmonised international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair trade practices in the food trade. http://www.codexalimentarius.org/

Government (FSA). This resource input is disproportionate when compared on a risk basis to many other food contaminants, for example the FSA spends approximately £2,400,000 on research and surveys into all other non-radiological chemical contaminants including additives, allergens and novel foods[27]. The FSA consider that it is possible to achieve the same objectives at lower cost, with savings to both business and UK Government without compromising food safety.

87. The continuation of the programme in its current form, which has evolved over many years, would fail to bring the programme in line with current international and UK best practice guidance which has been revised in recent years (see paragraphs 58 - 59).

Option 2 – FSA ceases radiological monitoring in food, and associated reporting

Costs

Industry

88. There will be no monetised costs to industry associated with terminating the programme.

Governments of crown dependencies

89. The subsidy for analysis of samples taken by the Channel Islands and Isle of Man would cease, at a cost of £41,191 per year. There is no food safety concern that these samples are currently addressing and there are no legal commitments to take these samples that the FSA is aware of. Part of their value is to provide data on background levels, but as the FSA holds many years of data, this resource can be used for comparative purposes, and further data adds little extra value.

90. In initial discussions, the Guernsey, Jersey and Isle of Man Governments have indicated that they would wish to continue sampling and analysis for radioactivity and so the costs would have to be picked up by these Governments if they wish to maintain the same level of sampling. For the purpose of this impact assessment, it has been estimated that the costs would be the same as the current subsidy. However, the actual costs are likely to be higher than this as the respective Governments would have to set up their own programmes and would not be able to benefit from the economies of scale of being part of a larger programme.

Table 4 – Per annum cost to governments of crown dependencies

Government	Cost
Guernsey	£21,872
Isle of Man	£15,675
Jersey	£3,644
Total	£41,191

Government (FSA)

91. There will be no monetised costs to the FSA associated with terminating the programme.

Non-monetised costs

92. The UK would be in breach of the Euratom Treaty and the Basic Safety Standards Directive which may lead to infraction proceedings and a substantial fine on the UK Government. The UK would also be in breach of commitments made under the OSPAR Convention which may lead to loss of international reputation and potential legal proceedings by other parties

[27] Annual Report of the Chief Scientist 2011/12, Food Standards Agency 2011. http://www.food.gov.uk/science/sci-gov/chiefsci/csreps/

to the convention[28]. It is not possible to monetise the costs associated with these risks, but they would be expected to be significant.

Summary of all costs under Option 2

93. The total cost per annum under Option 2 is £41,191. Once these costs are discounted at a rate of 3.5% over ten years, we obtain a present value of £354,559, as shown below in Table 5.

Table 5: Summary of all costs under Option 2

	Year 0	1	2	3	4	5	6	7	8	9	Total	PV
Crown Dependency Subsidies	£41,191	£41,191	£41,191	£41,191	£41,191	£41,191	£41,191	£41,191	£41,191	£41,191	£411,910	£354,559

These figures represent costs not attributable to any legislation, Euratom Treaty or OSPAR Convention requirement.

Benefits

Industry

94. The FSA is able to recharge all costs related to the site monitoring programme from the nuclear sites under the polluter pays principle. This includes the costs for sample purchase, sample collection, analysis costs, programme management (contractor and FSA staff time) and publication costs (the RIFE Report). If monitoring ceases then these costs will be a saving to the nuclear sites. These costs are calculated using actual current contract costs for 2011/12 and staff time is based on work-recording records completed by FSA staff for the purpose of recharging.

Table 6 – Per annum benefits to nuclear industry (nuclear site operators)

Benefit to nuclear sites	Sample purchase	Sample Collection	Analysis cost	FSA Staff Costs	Publication Costs	Total Benefit
England	£80,250	£234,009	£1,034,795	£82,197	£153,670	£ 1,58,921
Wales	£7,488	£32,407	£129,594	£10,471	£19,576	£ 199,536
Total	£87,738	£266,416	£1,164,388	£92,668	£173,246	£1,784,457

These figures represent savings related to the BSS Directive and EPR10. (NB: These figures also include samples used for compliance with the OSPAR Convention, but the samples are also collected for other purposes and so no additional savings are attributable to the OSPAR Convention).

95. Dairies who supply milk as part of the non-site Euratom Treaty reporting provide these samples free of charge. Therefore, ceasing the current programme will result in a saving to these businesses equivalent to the cost of the milk provided. These costs have been calculated assuming a cost of 50p per litre.

Table 7 – Per annum benefits to dairies

Benefit to Dairy Industry	Sample costs
England	£840
Northern Ireland	£323
Wales	£180
Total	£1,343

[28] For example: Ireland v. United Kingdom ("OSPAR" Arbitration) in 2002: http://www.pca-cpa.org/showpage.asp?pag_id=1158

These figures represent savings under the Euratom Treaty Article 35/36.

Government (FSA)

96. The FSA will save the costs related to the current programme for the non-site related work which is not recharged to nuclear sites. These costs which consist of sample purchase collection, and analysis of samples not related to nuclear sites are calculated using actual current contract costs for 2011/12. It has been assumed that there will be no reduction in staff costs to the FSA for non-recharged work as this resource will be redistributed to other priorities within the FSA.

Table 8 – Per annum benefits to government (FSA)

Benefit to Government (FSA)	Sample purchase	Sample Collection	Analysis cost	Total Benefit
UK	£8,226	£33,344	£330,692	£372,262

These figures represent savings not attributable to any legislation, Euratom Treaty or OSPAR Convention requirement.

Non-monetised benefits

97. The FSA would save its total programme cost. These resource savings could be more appropriately re-deployed in other areas where there are greater food safety risk, potentially providing a benefit to consumers.

Summary of all benefits under Option 2

98. Table 9 below shows that the total benefit of Option 2, over a period of ten years, is £21,580,620, with a present value of £18,575,921[29].

Table9: Summary of all benefits under Option 2

	Year 0	1	2	3	4	5	6	7	8	9	Total	PV
Nuclear sites	£1,784,457	£1,784,457	£1,784,457	£1,784,457	£1,784,457	£1,784,457	£1,784,457	£1,784,457	£1,784,457	£1,784,457	£17,844,570	£15,360,046
Dairies	£1,343	£1,343	£1,343	£1,343	£1,343	£1,343	£1,343	£1,343	£1,343	£1,343	£13,430	£11,560
FSA	£372,262	£372,262	£372,262	£372,262	£372,262	£372,262	£372,262	£372,262	£372,262	£372,262	£3,722,620	£3,204,315
Total	£2,158,062	£2,158,062	£2,158,062	£2,158,062	£2,158,062	£2,158,062	£2,158,062	£2,158,062	£2,158,062	£2,158,062	£21,580,620	£18,575,921

Summary of net benefits

99. Net benefits are calculated by subtracting total costs from total benefits. The total net benefit of Option 2 is £21,168,710 over a period of ten years, with a present value of £18,221,362, as shown below in Table 10.[30]

Table 10: Summary of net benefits under Option 2

	Year 0	1	2	3	4	5	6	7	8	9	Total	NPV
Net Benefits	2,116,871	2,116,871	2,116,871	2,116,871	2,116,871	2,116,871	2,116,871	2,116,871	2,116,871	2,116,871	21,168,710	18,221,362

Risks

100. There would be no direct food safety risk to consumers from this option as the FSA would maintain prospective assessments as part of the permitting procedure which will continue to ensure levels of radioactivity released into the environment remain significantly below any

[29] The present value is calculated by applying a discount rate of 3.5%, in line with HM Treasury Green Book Guidance, http://www.hm-treasury.gov.uk/d/green_book_complete.pdf

[30] The present value is calculated by applying a discount rate of 3.5%, in line with HM Treasury Green Book Guidance, http://www.hm-treasury.gov.uk/d/green_book_complete.pdf

levels which could cause food safety concerns. However, there will be no retrospective monitoring of the food to provide reassurance that levels in food are actually low.

101. There is a risk that this could impact on food exports as the FSA's radiological monitoring programme, and associated publication in the RIFE Report, is used as evidence that food production in the UK is free from harmful levels of radioactivity in the certification of export health certificates and certificates of free trade. The FSA would instead refer to the UK's regulatory system (see paragraphs 33 – 37) as evidence that UK food is not contaminated but there is a risk that importing countries may not consider this satisfactory which could harm trade with these markets.

102. The UK would be at risk of infraction by the European Commission for non-compliance with the BSS Directive and Euratom Treaty, and there would be associated risks to the UK's international reputation because of this. There would also be wider reputational risks to FSA within the EU. It could appear that FSA is not committed to all areas of food safety. This could result in a loss of consumer confidence in food produced around nuclear sites.

103. In the event of a radiological incident or emergency, the UK's capability to respond to any food safety issues would be reduced. Firstly, the laboratories that analyse samples are likely to lose staff and expertise if a significant portion of the FSA's radiological programme stops, such that the radio-analytical market is diminished within the UK. If there was a radiological incident the specialist analytical capability may not be sufficient in the short term. In addition, the FSA would no longer hold contracts for radiological analysis such that we would have to consider how to obtain information and expertise during an incident.

104. There would be a reduction in the ability to detect non-compliance by the nuclear sites and the potential for food safety consequences. As stated in paragraph 48, the current programme has been successful in identifying increases in releases of radioactivity from nuclear sites which required additional food safety assessment.

Wider impacts

105. If neither the FSA nor any other organisation, carried out radiological food monitoring, the EA would not be able to calculate total dose as there would be no data on the food pathway component (see paragraph 12) which is required for compliance with the BSS Directive and EPR10. In this case, the UK would be in breach of this legal requirement, as previously outlined.

106. During initial discussions with the EA they have indicated that they would have to review what actions they could take, and would consider several options. These include carrying out some food monitoring themselves, or undertaking a fundamental review of what monitoring should be carried out in the UK by operators and regulators. However, either of these would require a significant project within the EA, the outcome of which is far from certain. For example, their understanding is that their current remit does not include food, and therefore they would be unable to recharge the nuclear sites for food monitoring. They would therefore either have to fund the entire cost of the programme from EA's budget, which they have indicated they do not think is sustainable, or would have to seek a change in remit from DEFRA, their parent department. Therefore, the impact of this option on the EA would be significant, and they have indicated that they do not support this option.

107. If the FSA no longer lead on the RIFE partnership, then the future of the joint report would not be clear. It is possible that the remaining partners will maintain RIFE in its current format, but they may equally discontinue it and publish separate reports. This would have the disadvantage that information on radioactivity in food and the environment would no longer be in a single co-ordinated report covering the whole of the UK demonstrating compliance with BSS Directive and showing in a transparent way exposure to radioactivity from the food chain. It should be noted that the RIFE Report is held in high esteem within

the radiological community and our partner agencies have indicated they are supportive of the FSA maintaining the lead for this project.

Option 3 – Optimised monitoring programme

Costs

Industry

108. The costs of an optimised monitoring programme would continue to be recharged to nuclear sites. Under the proposed programme, there would be 1 (of the 23) nuclear sites for which the cost would increase from approximately £670 to £5,800 per year. This is due to the introduction of aquatic samples chargeable to that site where previously these samples had been subsumed within the larger programme of a nearby site.

Governments of crown dependencies

109. The subsidy for analysis of samples taken by the Channel Islands and Isle of Man would cease, at a cost of £41,191 per year and these costs would have to be picked up by the Guernsey, Jersey and Isle of Man Governments if they wish to maintain the same level of sampling. There is no food safety concern that these samples are currently addressing, and there are no legal commitments to take them that the FSA is aware of. Part of their value is to provide data on background levels, but as the FSA holds many years of data, this can be used as a resource for comparative purposes, and further data adds little extra value.

110. It has been estimated that the costs would be the same as the current subsidy with the respective Governments becoming partners in the programme and providing a contribution equivalent to the current subsidy to cover the costs of analysis for their samples.

Table 11 – Per annum costs to governments of crown dependencies

Government	Cost
Guernsey	£21,872
Isle of Man	£15,675
Jersey	£3,644
Total	£41,191

These figures represent costs not attributable to any legislation, Euratom Treaty or OSPAR Convention requirement.

Government (FSA)

111. An optimised site monitoring programme would mean that some aquatic sampling or analysis, the data from which currently serves a dual purpose of site monitoring and compliance with the OSPAR Convention, would no longer be undertaken as part of the site programme. Therefore, the FSA would need to fund the cost of this extra work to continue to meet the OSPAR Monitoring Agreement. This will be an additional cost to the FSA of approximately £12,812.

Table 12 – Per annum cost to government (FSA)

Cost to Government (FSA) from additional OSPAR samples	Sample purchase	Sample Collection	Analysis cost	Total Benefit
UK	£477	£720	£11,615	£12,812

These figures represent costs attributable to compliance with requirements under the OSPAR Convention.

Non-monetised costs

112. There are no non-monetised costs identified for this option.

Summary of all costs under Option 3

113. The total per annum cost under Option 3 is £59,133, with a present value over ten years of £508,998, as shown in Table 13 below.

Table 13: Summary of all costs under Option 3

	Year 0	1	2	3	4	5	6	7	8	9	Total	PV
Crown Dependency Subsidy	£41,191	£41,191	£41,191	£41,191	£41,191	£41,191	£41,191	£41,191	£41,191	£41,191	£411,910	£354,559
Industry	5,130	5,130	5,130	5,130	5,130	5,130	5,130	5,130	5,130	5,130	51,300	44,157
FSA	12,812	12,812	12,812	12,812	12,812	12,812	12,812	12,812	12,812	12,812	128,120	110,282
Total	**£59,133**	**£59,133**	**£59,133**	**£59,133**	**£59,133**	**£59,133**	**£59,133**	**£59,133**	**£59,133**	**£59,133**	**£591,330**	**£508,998**

Benefits

Industry

114. The proposed optimised monitoring programme would be significantly smaller than the current programme, and the costs recharged to nuclear sites as a whole would reduce by £883,000, which is approximately half of the current costs. The relative changes for the individual nuclear sites would vary, but 22 of the 23 nuclear sites would see reduced costs. The typical reduction is around 40-50% of the current cost, but varies in a range from 0% and 78%.

115. It is estimated that the optimised programme would take a similar amount of FSA staff time, as the time required to manage the programme is not directly proportional to the numbers of samples taken and so the benefits quoted are from changes in contractual costs only.

Table14 – Per annum benefits to nuclear industry (nuclear site operators)

Benefit to nuclear sites	Sample purchase	Sample Collection	Analysis cost	FSA Staff Costs	Publication Costs	Total Benefit
England	£59,539	£175,838	£539,206	£0	£0	£774,583
Wales	£5,758	£26,083	£76,623	£0	£0	£108,464
Total	£65,297	201,921	£615,829	£0	£0	£883,047

These figures represent savings related to the BSS Directive and EPR10.

Government (FSA)

116. The FSA would cease the components of the current FSA-funded part of the programme that are not designed to meet statutory requirements. This includes crop, animal and aquatic samples taken away from nuclear sites for general surveillance. The subsidies for analysis of samples taken by the Channel Islands and Isle of Man would also cease. The remaining projects to monitor milk and mixed diet will be reviewed to ensure they are focused on satisfying Euratom Treaty requirements. These cost savings would be a total benefit of £251,615 to the FSA.

Table 15 – Per annum benefits to government (FSA)

Benefit to Government (FSA)	Sample purchase	Sample Collection	Analysis cost	Total Benefit
UK	£7,826	£15,841	£227,948	£251,615,

These figures represent savings not attributable to any legislation, Euratom Treaty or OSPAR Convention requirement.

Non-monetised benefits

117. The FSA would reduce its part of the programme costs. These resource savings could be more appropriately re-deployed in other areas where there are greater food safety risk, potentially providing a benefit to consumers.

Summary of all benefits under Option 3

118. The total per annum benefit under Option 3 is £1,134,662, with a present value of £9,766,815 over a period of ten years, as shown below in Table 16.

Table 16: Summary of all benefits under Option 3

	Year 0	1	2	3	4	5	6	7	8	9	Total	PV
Industry	£883,047	£883,047	£883,047	£883,047	£883,047	£883,047	£883,047	£883,047	£883,047	£883,047	£8,830,470	£7,600,992
FSA	£251,615	£251,615	£251,615	£251,615	£251,615	£251,615	£251,615	£251,615	£251,615	£251,615	£2,516,150	£2,165,823
Total	**£1,134,662**	**£1,134,662**	**£1,134,662**	**£1,134,662**	**£1,134,662**	**£1,134,662**	**£1,134,662**	**£1,134,662**	**£1,134,662**	**£1,134,662**	**£11,346,620**	**£9,766,815**

Summary of net benefits

119. Net benefits are calculated by subtracting total costs from total benefits. The total per annum net benefit under Option 3 is £1,075,529, with a net present value of £9,257,816 over a period of ten years, as shown in Table 17 below.

Table 17: Summary net benefits under Option 3

	Year 0	1	2	3	4	5	6	7	8	9	Total	NPV
Net Benefits	£1,075,529	£1,075,529	£1,075,529	£1,075,529	£1,075,529	£1,075,529	£1,075,529	£1,075,529	£1,075,529	£1,075,529	£10,755,290	£9,257,816

Risks

120. There may be the perception that the extent of monitoring is being reduced because of government cost savings. This may raise public concern that food safety is no longer being given the highest priority and result in a loss of consumer confidence for food produced near nuclear sites. However, the FSA is confident that the optimised programme meets the UK's legal requirements and applies current best practice. The programme will therefore continue to be robust and provide the ability to demonstrate that doses to consumers are below legal limits.

Wider impacts

121. Optimisation of the programme will result in a decrease in the number and types of samples taken around each site. It may also mean that different types of food are collected each year. This may lead to fluctuations in the reported dose each year as the samples of one food type collected one year may have different levels of radioactivity to a different food type collected in the subsequent year. This may also affect the ability to use the data to analyse for trends over time.

122. The FSA would have sufficient flexibility in the optimised programme to be able to respond if intelligence of a possible food safety concern is received or there is a particular policy need, by changing the routine sampling, analysis or including extra samples.

123. A targeted programme, with a clear set of objectives and clear basis for the sampling plan, would continue to offer reassurance to UK consumers, especially those living near nuclear sites, that the food they eat is safe to eat. The nuclear site operators have previously indicated they find value in the FSA's monitoring programme, as it is independent data that can be used to reassure government and the public that their operations are within agreed limits.

124. The national monitoring programme would continue to demonstrate food production in the UK is free from harmful levels of radioactivity and could still be used as evidence in the certification of export certificates.

Specific impact tests

Competition assessment

125. This policy is not expected to either directly or indirectly have any impact on competition.

Small firms impact test

126. No small firms are involved in the nuclear industry, the primary group affected by this proposal.

127. Micro, small and medium businesses are involved in the supply of samples to the FSA programme on a voluntary basis. In the majority of cases, samples are purchased from suppliers. The quantity of samples provided by any individual supplier is not significant and any changes to the programme are unlikely to affect sample suppliers. Where samples are purchased it is assumed the suppliers will instead sell the product on the open market and achieve a similar price as that paid by the FSA.

Sustainability

128. The monitoring programme does not itself provide a food safety measure as results are only available sometime after the food will have been consumed and so it can only assess the dose that consumers have already received. For this reason, the prospective assessments, as part of the permitting procedure, are used to ensure permitted radioactive discharges remain significantly below any levels which could cause food safety issues. Therefore, changes to the monitoring programme will have no food safety implications.

129. Impacts under the 3 pillars of sustainable development (environmental, economic and social) have been, and continue to be, considered in the preparation of the impact assessment. Option 3 is the preferred option because it minimises the costs of industry and the public sector by removing regulatory burdens which are not required.

Equality impact

130. The FSA does not foresee any impact in terms of equality.

Consultation questions

Q1: Does the current programme of radiological assessments, monitoring and reporting provide the data and reassurance on food safety that you require? If not, please provide evidence to show why you disagree.

Q2: Do you consider that an optimised programme focused on providing data sufficient to calculate the total dose and meeting the UK's legal and international obligations (Option 3) would continue to provide the data and reassurance on food safety that you require? If not, please provide evidence to show why you disagree. (see paragraphs 67 to 80)

Q3: Do you agree with the proposal in Option 3 to remove all aspects of the programme for which there is no legal or international obligation (e.g. surveillance of food remote from nuclear sites)? If not, which aspects of the programme would you like to see retained and why? (see paragraph 5, 49 and 78)

Q4: Do you agree with the proposal in Option 3 for the FSA to maintain an independent monitoring programme with costs recharged to industry rather than imposing a requirement for site operators to take the samples and report the data to the FSA? If not, please set out your reasons for alternative arrangements. (see paragraph 74)

SPECIFIC IMPACT TESTS

Note: the Health and Wellbeing specific impact test is not in the list, because the whole of an FSA IA focuses on food safety in the health context.

Type of test and link to guidance (Double click on each of the headings to follow link)	Click on a box for EACH row to show if the test is relevant or not:	
	Relevant	Not relevant
Competition assessment	☒	☐
Small firms impact test	☒	☐
Sustainability:		
Economic impact	☒	
Social impact	☒	
Environmental impact	☒	
Carbon impact	☐	☒
Equality impact	☐	☒
Justice impact	☐	☒
Rural proofing	☐	☒
Human rights	☐	☒
Privacy impact	☐	☒
Creation of new criminal offence	☐	☒
Impact on powers of entry	☐	☒

Annex I: How risks from radioactivity are calculated – use of 'dose'

131. The Food Standards Agency (FSA) is responsible for food safety throughout the UK (under the Food Standards Act 1999). As part of this role, the FSA routinely assesses the risk to human health from radioactivity in food. This risk is assessed by calculating the radioactive dose received by consuming that food.

132. Doses are calculated by multiplying the concentration of a radionuclide in a food, by the amount of food eaten, usually over a year, multiplied by a constant for each radionuclide called a 'dose coefficient'. Dose coefficients are a measure of how damaging the radionuclide is to human health and also reflect how much will be taken into the body through the gut ('the ingestion route'). Doses are measured in sieverts (Sv), and often reported as millisieverts (mSv; where 1 Sv = 1000 mSv). In radiological protection, it is assumed that dose is directly proportional to the risk to health, so the higher the dose, the greater the risk of harmful effects (e.g. the risk of developing cancers).

133. The sources of radioactivity considered in the monitoring regime are primarily gaseous and liquid wastes from nuclear sites. The main pathways of effect of this radioactivity on the human body are from ingestion of foodstuffs and external exposure from contaminated materials in the aquatic environment (as well as a number of more minor pathways). In addition, direct radiation from sources on the site premises is also included in a calculation of 'total dose' (from food and the environment).

134. The concept of the 'representative person' is used for assessing doses to members of the public[1]. This is defined as 'an individual receiving a dose that is representative of the more highly exposed individuals in the population'. In the FSA's dose assessments, the representative person is taken to be someone who eats large quantities of locally-grown food. Therefore, information on consumption rates is needed for dose assessments which are determined by the FSA's site-specific dietary habit surveys. Data for the habit surveys are collected primarily by direct interviews with potential high-rate consumers. **This work has been reviewed internally by the FSA and will continue; none of the options proposed in this review will alter the actions and subsequent recharges based on this aspect of the programme.**

135. Dose calculations also take account of the age of the individual; through information on differing eating habits, and also different dose coefficients. A risk assessment is then usually carried out on the most affected age group.

136. The mean dose received by the 'representative person' is compared with the dose limit. The relevant dose limit for members of the public is 1 mSv per year (from a combination of food and environmental pathways); set out in Article 13 of the Basic Safety Standards Directive[2].

[1] The 2007 Recommendations of the International Commission on Radiological Protection, (ICRP Publication 103; 2007)

[2] *Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.* OJ. 1996, 39(L159): 1 – 114. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1996L0029:20000513:EN:PDF

Annex II: Outline of optimised sampling and analysis programme (as applied in Option 3)

Site-specific monitoring to calculate total dose, in support of the requirement in the Basic Safety Standards Directive[3]

The principle of a tiered approach for site monitoring

137. The Technical Guidance Note 24, which is based on IAEA guidance of best practice, provides a range of sample sizes and frequency of sampling for all sample types (including food) for both the regulators and operators. However, there is little to assist with selecting the part of the range to pick for each sample type. Therefore, a three-tiered system has been proposed using retrospective doses calculations (i.e. the food component of the total dose assessment for a site as published in RIFE) as the markers for differentiating within the bands. The criteria will be applied for both the aquatic and terrestrial pathways separately.

Table A1: Selection criteria and current allocation of sites

Tier	Dose criteria for inclusion to tier	Aquatic dose	Terrestrial dose
Top	Food component of dose pathway under consideration has exceeded 100 μSv for one or more of the previous 3 reported years	Sellafield	None
Middle	Food component of dose pathway under consideration has been at least 20 μSv for one or more of the previous 3 reported years but not above 100 μSv for any of those 3 years	None	Sellafield
Bottom	Food component of dose pathway under consideration has not exceeded 20 μSv within previous 3 reported years and there are no indications that the food dose is likely to increase the next year	All other sites	All other sites

138. Applying these bandings to the sample range in the Technical Guidance Note 2, those sites in the bottom tier will require the minimum of the range, those in the middle tier will require the median of the range and those in the top tier will require the maximum of the range.

139. Where sites are transferring from active operation, like power generation, into the early stages of decommissioning, the tiered approach will allow for a more flexible programme to be introduced, with sites moving between tiers when trigger levels are reached. This would build on the current yearly reviews where small incremental changes have always been made. This flexibility can work for potential increased requirements as well as if the new nuclear build programme required it. However, for the purposes of this Impact Assessment, it has been assumed that no sites will change tier over the next 10 years.

[3] *Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.* OJ. 1996, 39(L159): 1 – 114. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1996L0029:20000513:EN:PDF

[4] Environmental Radiological Monitoring: Environment Agency, Food Standards Agency & Scottish Environment Protection Agency, 2010. *Radiological Monitoring Technical Guidance Note 2*. http://publications.environment-agency.gov.uk/PDF/GEHO0811BTVY-E-E.pdf

Application of the tiered approach to nuclear site sampling

140. The principles above have been used to set out the following model for the number of samples for each nuclear site for the purpose of providing indicative costs for the Impact Assessment. However, in practice these may vary depending on the evidence from surveys of habits of local people, or on the basis of modelling assessments. For example, if there is no identified production of a food type within an area which modelling results suggest could be affected by discharges from the site, then the sample size could be zero.

141. The Technical Guidance Note 2 has the following categories of foods which should be sampled around nuclear sites:

- Fish – Marine and freshwater
- Crustaceans & Molluscs – Marine and freshwater
- Seaweed / Aquatic Vegetables
- Milk and dairy products
- Meat and meat products
- Poultry and Eggs
- Fruit and Vegetables
- Cereals (crops)
- Wildlife / Game

Aquatic components

Fish – Marine and freshwater

142. The Technical Guidance Note 2 provides a range for the Regulator of 2 to 10 samples per year per site. Therefore, the bottom tier sites will have 2 samples, the middle tier would have 5 samples and a top tier site will have 10 samples.

Crustaceans & molluscs – Marine and freshwater

143. The Technical Guidance Note 2 provides a range for the Regulator of 2 to 20 samples per year per site. Therefore, the bottom tier sites will have 2 samples, the middle tier would have 10 samples and a top tier site will have 20 samples.

Seaweed / aquatic vegetables

144. The Technical Guidance Note 2 provides a range for the Regulator of 1 to 16 samples, where seaweed is consumed or used as fertiliser, based on habit surveys and availability of species. The specifications for seaweed have been applied to all aquatic vegetation that is consumed. Therefore, subject to habit surveys, the bottom tier sites will have 0 or 1 sample, the middle tier will have up to 8 samples and a top tier site will have up to 16 samples.

145. Habit surveys have shown that edible seaweed is currently not an identified pathway at any existing nuclear sites. With regard to seaweed use as a fertiliser, no significant finds have been noted for this work and at Sellafield, the seaweed sea to land pathway has resulted in a dose of > 0.005 mSv per year to high rate consumers only on one occasion (0.069 mSv in 2005). Therefore, the proposal is to cease all seaweed samples in relation to food.

146. Currently, other aquatic vegetables sampled are one sample each of samphire at Sellafield, Bradwell, Heysham and Springfields, leaf beet at Bradwell and sea kale at Dungeness. For the purpose of this Impact Assessment, these existing samples will be maintained as they have been identified as pathways from local habit surveys, although Bradwell will be reduced to one sample per year. No additional samples will be added. However, in practice this may change based on future habit surveys and risk assessments.

Table A2: Aquatic samples per site

Tier	Site	Fish	Crustaceans and molluscs	Aquatic vegetables	Seaweed
Top	Sellafield	10	20	1	0
Middle	N/A	5	10	As identified by habit surveys	
Bottom	Dungeness, Bradwell, Heysham and Springfields	2	2	1	0
	Trawsfynydd	2	0*	0	0
	All other sites (except sites listed under "Other")	2	2	0	0
Other	Combined sampling for "Thames sites" (Aldermaston, Amersham and Harwell) [#]	1	1	0	0
	Ascot, and Derby[+]	0	0	0	0
Total	**All Sites**	**45**	**53**	**5**	**0**

* The Trawsfynydd site discharges into a fresh water lake and crustaceans and molluscs are not an identified exposure pathway.

[#] Aldermaston, Amersham and Harwell all discharge into the Thames river system and therefore the same samples can be used to assess the discharges from all three sites.

[+] Ascot (Imperial College) and Derby have no aquatic samples as there are no identified exposure pathways

Terrestrial components

Milk and dairy products

147. Currently, milk samples are collected weekly and typically bulked into quarterly samples for analysis. Where short-lived nuclides are of interest, samples may be analysed weekly or

monthly. For certain analyses which are more expensive, samples may be bulked into 6-month or annual samples.

148. It is proposed that the current analytical regime described above will continue. However, the proposal is to reduce collections for most sites to monthly instead of weekly, except where short lived nuclides are of particular interest. Currently, samples are collected weekly to account for changes in the feeding patterns of cattle throughout the year (e.g. feeding on silage during winter months). However, as most samples are bulked quarterly, monthly samples will be more than sufficient to maintain year round coverage.

149. The Technical Guidance Note 2 provides a sampling range for the Regulator of between 5 and 88 samples per year per site. For this proposal, the range has been applied only to quarterly samples and so represents a range of between 2 and 22 farms. Therefore the bottom tier sites will have 2 farms (8 quarterly analyses), the middle tier sites will have 11 farms (44 quarterly analyses) and a top tier site would have 22 farms (88 quarterly analyses). Where periods other than quarterly are used, the actual number of analysed samples will vary.

150. Dairy products are not routinely sampled as analysis of the raw milk can be adequately used to assess the dose.

Table A3: Milk samples per site

Tier	Site	Farms	Collection	Bulking regime / Total samples analysed per year
Top	N/A	22	As required	88 quarterly
Middle	Sellafield	11	4 farms weekly 7 farms monthly	208 weekly 132 monthly 44 quarterly 20 biannual 10 annual
Bottom	Amersham	2	Weekly	26 monthly 8 quarterly
	Springfields	2	Monthly	2 annual
	Cardiff	2	Monthly	24 monthly 8 quarterly
	Drigg	2	Monthly	24 monthly 8 quarterly 4 biannual
	Capenhurst	2	Monthly	8 quarterly 4 biannual 2 annual
	Aldermaston	2	Monthly	8 quarterly 2 annual
	All other sites (except sites listed under “Other”)	2	Monthly	8 quarterly
Other	Ascot, Barrow, Derby and Devonport*	0	N/A	N/A
Total	**All Sites**	**47**		

* Ascot (Imperial College), Barrow, Derby and Devonport are minor sites with no available milk farms within an area which could be affected by site discharges and so milk is not an identified exposure pathway. The FSA is not proposing to introduce milk sampling to these sites.

Meat and meat products

151. The Technical Guidance Note 2 provides a range for the Regulator of 0 to 32 samples per year per site. Therefore, the bottom tier sites will have 0 samples, the middle tier will have 16 samples and a top tier site would have 32 samples.

Poultry and eggs

152. The Technical Guidance Note 2 provides a range for the Regulator of 2 to 32 samples per year per site, based on habit surveys of poultry scavenging on contaminated land e.g. sea to land transfer or sea-washed pastures. In addition, the Regulator should take 2+ as part of national programme for backgrounds. Currently, no habits surveys identify a notable pathway for poultry. Eggs are only sampled at Sellafield. Therefore, the proposal is to maintain 2 egg samples at Sellafield as part of the national programme.

Fruit and vegetables

153. The Technical Guidance Note 2 provides a range for the Regulator of 1 to 14 samples per year per site. Therefore, the bottom tier sites will have 1 samples, the middle tier will have 7 samples and a top tier site would have 14 samples.

Cereals (crops)

154. The Technical Guidance Note 2 provides a range for the Regulator of 1 to 2 samples per year per site. Therefore, the bottom tier sites will have 1 sample, the middle tier and top tier will have 2 samples.

Wildlife / game

155. The Technical Guidance Note 2 provides a range for the Regulator of 0 to 10 samples per site based on habit surveys of animals grazing contaminated land e.g. sea to land transfer or sea-washed pastures. Therefore, subject to habit surveys, the bottom tier sites will have 0 or 1 sample, the middle tier will have up to 5 samples and a top tier site would have up to 10 samples.

156. Currently, Sellafield have samples of Rabbit (x1), Pheasant (x1), Deer (x1) and Wood Pigeon (x2); Bradwell, Springfield and Aldermaston have one sample each of Rabbits; and Heysham and Springfields have one sample each of Wildfowl. For the purpose of this Impact Assessment it has been assumed that these existing game samples will be maintained. However, in practice this may change based on future habit surveys and risk assessments.

Table A4: Terrestrial non-milk samples per site per year

Tier	Site	Meat and meat products	Poultry and eggs	Fruit and vegetables	Cereals	Game
Top	N/A	32	32	14	2	10
Middle	Sellafield	16	2	7	2	5
Bottom	Aldermaston, Bradwell and Heysham	0	0	1	1	1
	Springfields	0	0	1	1	2
	All other sites	0	0	1	1	0
Total	**All Sites**	**16**	**2**	**29**	**24**	**10**

Non-site monitoring to satisfy EURATOM Treaty

157. Commission Recommendation 2000/473/Euratom[5] provides outline guidance on monitoring recommended to be carried out by Member States and reported to the European Commission, under Articles 35 and 36 of the Euratom Treaty.

Euratom Treaty – Milk

158. Recommendation 2000/473/Euratom states that milk should be sampled across a dense and a sparse network[6]. For the dense network, Member States must report caesium-137 (Cs-137) and strontium-90 (Sr-90) and for the sparse network must in addition report potassium-40 (K-40).

159. In addition to the reported analytes, the FSA also currently analyses for tritium (H-3) and carbon-14 (C-14) at all dairies. The proposal is to cease these additional analytes as there is no food safety benefit in continuing to analyse for these radionuclides remote from nuclear sites.

160. Samples will be taken and analysed monthly from all dairies in England and Wales. In Northern Ireland, the dense network of dairies is rotated so that samples from individual dairies are taken every two-months.

[5] Commission Recommendation on the application of Article 36 of the Euratom Treaty concerning the monitoring of the concentrations of radioactivity in the environment for the purpose of assessing the exposure of the population as a whole. OJ. 27 July 2000, 2000/473/Euratom. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:191:0037:0046:EN:PDF

[6] Recommendation 2000/473 defines the dense monitoring network as a monitoring network comprising sampling locations distributed throughout the Member State's territory such as to allow the Commission to compute regional averages for radioactivity levels in the Community.
The sparse monitoring network is defined as a monitoring network comprising for every region and for every sampling medium at least one location representative of that region. At such locations high sensitivity measurements should be performed thus giving a transparent representation of actual levels and trends of radioactivity levels.

Table A5: Current dairy numbers in England, Wales and Northern Ireland

	Dense Network # dairies	Samples per dairy per year	Sparse Network # dairies	Samples per dairy per year	Samples analysed per year
England	13	12	1	12	168
Wales	2	12	1	12	36
Northern Ireland	5	6	1	12	42
Total	**20**		**3**		**246**

Euratom Treaty –Mixed diet

161. For mixed diet, the FSA takes canteen meals from locations throughout the UK and analyses the total meal for caesium-137 (Cs-137) and strontium-90 (Sr-90) to be reported to the European Commission. This will be maintained to demonstrate continued compliance with Recommendation 2000/473/Euratom.

162. In addition, the FSA also currently analyses for carbon-14 (C-14) and the proposal is to cease these additional analyses as there is no food safety benefit in continuing to monitor for this radionuclide remote from nuclear sites.

Table A6: Canteen locations

	Canteens sampled quarterly	Canteens sampled annually	Total samples analysed per year
England	1	4	8
Wales	1	1	5
Northern Ireland	1	1	5
Scotland	0	2	2
Total	**3**	**8**	**20**

Non-site monitoring to satisfy OSPAR Convention

163. The programme would include samples of fish and molluscs to satisfy obligations for the OSPAR Convention, although the sampling schedule would be optimised to ensure it is in line with current OSPAR commitments and guidance.

164. In 2011, OSPAR published an Agreement on a Monitoring Programme for Concentrations of Radioactive Substances in the Marine Environment[7]. The Agreement sets out the basis for future monitoring by the OSPAR Contracting Parties of concentrations of radioactive substances. It specifies the locations where samples should be taken and frequency of sampling.

165. The Agreement specifies the monitoring of the artificial radionuclides caesium-137 (Cs-137) in fish and molluscs and plutonim-239/240 (Pu-239/240) in Molluscs. It also specifies the monitoring of the naturally occurring radionuclides polonium-210 (Po-210) and lead-210 (Pb-210) in both fish and molluscs.

[7] Agreement on a Monitoring Programme for Concentrations of Radioactive Substances in the Marine Environment (Update 2011).OSPAR, 2011. Agreement 2005-08. 1.
http://www.ospar.org/documents/dbase/decrecs/agreements/05-08_monitoring%20radioactive%20substances.doc

Table A7: OSPAR Sample locations in the Agreement on a Monitoring Programme for Concentrations of Radioactive Substances in the Marine Environment

Location	Fish	Mollusc
Bradwell	2	
Capenhurst*		4
Hartlepool#	2	2
Heysham*#		4
Sellafield#	3	12
Sizewell	2	
Springfields		2
Winfrith		1
Wylfa#		2
Total	**9**	**27**

* Capenhurst and Heysham each require 2 additional mollusc samples beyond those set out in the tiered approach (Table A2). The cost for these additional samples and their analysis will be borne by the FSA.

Hartlepool, Heysham, Sellafield and Wylfa all require additional analysis of samples specifically to meet OSPAR requirements, but these can be undertaken on samples already collected under the tiered approach (Table A2). The cost for these additional analyses will be borne by the FSA.

UK surveillance

166. The FSA currently takes crop, vegetable and animal samples remote from nuclear sites to provide information on background levels. The FSA also takes aquatic samples around the UK coastline to provide information on background levels and far field affects of Sellafield discharges.

167. These samples are not required for regulatory or legislative reasons and the data already collected over the last 35 to 60 years can be used should there be a need for background data in the future. Therefore, the proposal is to cease these aspects of the programme.

Annex III: Options considered but not taken forward to full impact assessment

Option summary	Detail	Advantages	Disadvantages	Proposal
Programme transferred to another public body to manage	EA, Local authorities or HPA manage the programme with the FSA's input on programme design. The legal requirement for ensuring the safety of food through the assessment of data significance remains with the FSA	• Significant FSA resources freed up. • If EA did it then it would mirror what SEPA do (programmes balanced)	• LAs – cost of training for consistency to factor in & previously perceived as a low priority – risk could remain as such • EA - could not currently reclaim costs for programme • Still require resource to advise on programme and significance • No direct control over strategic capability • Loss of capability within FSA in the event of a nuclear incident	Would still require an advisory role from FSA. Other organisations may not have the capability to recharge for food sampling and analysis and so this option could result in increased costs to Government, contrary to the 'polluter pays' principle.
Programme transferred to site operators to manage and report data to the FSA	Periodic check-sampling of operator's programme would be needed to verify site operator's outputs. FSA would still be involved for interpretation and reporting on the results.	• Significant FSA resources freed up; nuclear sites pay directly so potential savings or at least more direct controls of costs; consistency with approach for discharge monitoring	• Additional burden on business to report data • Perception of being run by industry; would require change in capability for sites • Loss of capability within FSA in the event of a nuclear incident • No MCERTS[1] equivalent currently available	There would be a strong public perception issue with this Option and the site operators are not currently equipped to be able to run such programmes but with the development of MCERTS equivalent this would be possible.

[1] MCERTS is the Environment Agency's Monitoring Certification Scheme. It provides the framework for businesses to meet the EA's quality requirements. If businesses comply with MCERTS the EA can have confidence in the monitoring of emissions to the environment. http://www.environment-agency.gov.uk/business/regulation/31829.aspx

Option summary	Detail	Advantages	Disadvantages	Proposal
Indicator samples only	Instead of food samples, a selected number of indicator samples (such as grass and soil) are analysed. Food chain modelling could be used for dose impact assessment.	• Indicator samples cheaper than food samples • Samples and analysis can be shared with environment agencies • Fewer seasonal issues to deal with • Increased likelihood that samples could be obtained from required location	• Modelling of indicator samples will make dose calculations less robust; • Some foods cannot be adequately modelled from indicator data; • Likely to offer less reassurance to consumers	Does not meet objective of compliance with legal and international obligations.
Year-on-year	Maintain the current programme scale per site but only visit a few sites each year to form a rolling programme.	• Cheaper with some staff resource saving; Reduces resources overall but still allows same current scale for each site; • Good comprehensive cover when turn of site; • Potentially fits with habit survey programme cycles	• No doses for most sites each year and so doesn't comply with BSS Directive • Limited strategic capacity likely	Not considered adequate for *total* dose calculations. May be methods that can be used (such as in-fills of data from previous years) but weak evidence base. Does not meet objective of compliance with legal and international obligations.
Statistical relevance for samples	Use the number of replicates for each sample at each site that would ensure statistical significance for concentrations of radionuclides for doses assessments.	• Consistent criteria for programme; • Robust reason for selection	• To get statistical certainty would require large increase in sample numbers and therefore significant increase in costs; • Would require more resource to manage and large number of samples would push lab capacity	Not considered value for money. Significantly less proportionate compared to the risk.