

# **Consultation Report on the Safety Toaster Application for Justification**

**Prepared by the DTI-Business Relations for  
consideration by the DTI's S.o.S.**

**Dated 22 June 2005**

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## **Part I: General Background**

### **A) About the Safety Toaster Application**

#### Nature of Application

1. On 18<sup>th</sup> February 2005 the applicant submitted his request for justifying the use of a smoke detector in a toaster under the existing practice category for smoke detectors. He provided details of the product's design, benefits and background (patent filing history, media coverage, governmental funding and manufacturing arrangements).

#### Information to the Applicant

2. We (herewith meaning the DTI) indicated a likely response to the request by mid-May once the obligatory consultation was complete. HPA-RPD's subsequent radiation dosage assessment concluded the analysis on the balance between benefits and detriments for the safety toaster.
3. We also explained to the applicant that there are 2 key aspects to consider: the first looking at whether radiation is used in an acceptable way (known as "justification"), and then secondly checking that the product is safe/acceptable for the market and complies with other regulation that may come into play (known as "prior authorisation"). The Justification Regulations 2004 deal specifically with the first aspect i.e. justification or acceptable use of radiation in principle.
4. We made the applicant aware that consultation is case-by-case so looks closely at the merits of an individual product. Some points that arise during consultation relate to justification; others relate more specifically to the prior authorisation process.
5. We further highlighted that we also need to ensure that any decisions relating to justification are more widely consistent across designated Justifying Authorities, so that the application of the Justification Regulations 2004 is uniform and transparent across the UK.

### Prior Authorisation in conclusion to Justification

6. Justification comes before prior authorisation because if the use of radiation is in itself unacceptable, the product can never be made fit for the market (see also para 12 ff. of this consultation report on “What cannot be considered and is banned outright”).

### First case for DTI since new Justification Regulations started

7. The safety toaster application is the first practice presented for justification to the DTI since the Justification Regulations 2004 came into force on 2nd August 2004.
8. The accompanying Defra guidance to the Justification Regulations 2004 (issued November 2004; herewith known as “Defra Guidance”) explains that the Justification Regulations 2004 provide a framework for justification decisions (cf. Defra Guidance para 1).
9. Defra Guidance emphasises “it is important to remember that a decision that a class or type of practice is justified does not in itself allow practices of that class or type to be operated. There are other regulatory provisions that need to be met (i.e. IRR99, RSA93 and the transport regulations) and these control the manner in which a practice is operated in order to ensure compliance with the ICRP principles of optimisation and dose limitation” (cf. Defra Guidance para 11).
10. Any decision under the Justification Regulations 2004 on a radiation practice (including that for the safety toaster) therefore needs to be considered in the broader context of existing regulations to achieve an overall consistent and compatible approach.
11. Defra Guidance goes on to explain that a practice relates to “the production, processing, handling, use, holding, storage, transport, import to and export from the Community and disposal of radioactive substances” (cf. Defra Guidance para 18 with reference to the EU Basic Safety Standards Directive article 2a). These are therefore the areas where the ICRP principles of optimisation and dose limitation apply for the safety toaster.

### What cannot be considered and is banned outright

12. The Justification Regulations 2004 relate to the EU Council Directive 96/29 Euratom of 13 May 1996 (herewith known as EU

BSS i.e. EU Basic Safety Standards). Under its General Principles (Chapter 1, Article 6 para 5), the EU BSS states: “Member States shall permit neither the deliberate addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics nor the import or export of such goods”.

**13.** Defra guidance makes clear that under EU BSS such cases are automatically ruled out and not eligible for a justification process (see para 14 of Defra Guidance). Foodstuffs are not mentioned in the Justification Regulations 2004.

Whether the safety toaster can be considered for justification in any event

**14.** We are currently considering if Article 6, para 5 of the EU BSS binds us, even though it has not been included in the Justification Regulations 2004. Assuming we are bound, we understand that the outright ban on the “deliberate addition of radioactive substances in the production of foodstuffs” to mean that no radiation may be added to foodstuffs during their production, rather than equating to an outright ban on the use of radiation during production processes for food.

## **B) About the Safety Toaster Consultation**

The Justifying Authority for the Safety Toaster

**15.** The applicant requested a determination under the existing justification-class or type no.15 (safety devices: use of ionising radiation in smoke and fire detectors and other safety instruments), as set out in Annex 3 of Defra Guidance, where the DTI is identified as the lead department or Justifying Authority.

Whom the Justifying Authority consulted on the Safety Toaster

**16.** The Justifying Authority must call on obligatory consultees to help reach a verdict. We therefore consulted with all obligatory parties and kept all members of the Justification Liaison Group (JLG) informed throughout.

Obligatory Consultees for the Safety Toaster

**17.** The obligatory parties for consultation foreseen in the Justification Regulations 2004 (no. 18) are: the devolved administrations together with the Health and Safety Executive (HSE), the Food Standards Agency (FSA), the National Radiological Protection Board (now part of the Health Protection Agency and known as the Radiation Protection Division), the Environment Agency (EA), the

Scottish Environment Protection Agency (SEPA) and the Department of the Environment for Northern Ireland (DOENI).

#### Additional Consultees for the Safety Toaster

18. We also consulted with the Office of the Deputy Prime Minister (ODPM) because of their fire safety remit and responsibility.

#### Full Consultation with Devolved Administrations

19. As foreseen in the Concordat on the implementation of the Justification Regulations 2004 (herewith referred to as “the Concordat”), as well as in accordance with the obligation in the Justification Regulations 2004, we consulted fully with the Devolved Administrations to ensure that the outcome of the safety toaster consultation would be applicable and consistent across the whole of the UK.

20. The Devolved Administrations consist of the Department of Environment in Northern Ireland (DOENI), the National Assembly for Wales (NAW) and the Scottish Executive (SE).

#### The Justification Liaison Group (JLG)

21. Parties to the Concordat (UK Government Departments and the Devolved Administrations) jointly set up a Justification Liaison Group (JLG) to facilitate common agreement on implementing the Justification Regulations 2004.

22. The following UK Government Departments provide JLG members: Defra (Department for Environment, Food and Rural Affairs); DoH (Department for Health); DTI (Department of Trade and Industry); Department for Transport (DfT); Home Office (HO).

#### How the JLG operates

23. The JLG has not yet formally convened: the safety toaster is only one of two cases altogether that were submitted after the Justification Regulations 2004 came into force last August.

24. The Concordat places emphasis on continuous co-operation and close communication: it sets out the ways the JLG can reach agreement and resolve differences, depending on what the Justifying Authority has concluded from the obligatory consultation exercise.

## **Part II: The Justification Process**

### **A) What Justification entails**

#### Purpose and principles of the Obligatory Consultation

25. The Justification Regulations 2004 relate to the EU BSS. The EU BSS both sets out the justification principles for the deliberate use of radiation and calls on Member States to set up prior authorisation schemes to ensure that the products which incorporate accepted use of radiation are also compliant with the overall regulatory framework and therefore ready for the market.
26. Determining an accepted use of radiation involves weighing the benefits with detriments and, in the event of justification, then assigning an approved category to the product (either new or existing) that gives an order of magnitude for its benefits compared to other acceptable radiation practices. In this way, similar orders of benefits are grouped together (as in the Annex to Defra guidance).
27. Justification for radiation practices recognises the inherent harm in radiation but looks to see what wider case can be made in favour of its use. Consultation across obligatory parties is an important part of seeking out economic, social or other benefits in relation to the health detriment caused by practices that result in exposure to ionising radiation (cf. Defra Guidance para 2).

#### Distinguishing between Justification and Prior Authorisation

28. EU BSS (Article 4 1c) requires prior authorisation “for the deliberate addition of radioactive substances in the production and manufacture of consumer goods and the import or export of such goods”.
29. In the event of justification, the safety toaster, therefore, as a consumer good, must undergo prior authorisation before being allowed entry to the market. Prior authorisation is not set out in the Justification Regulations 2004, although Defra Guidance and the EU BSS both refer to it.
30. Whilst justification weighs up the overall benefits against the detriments in using radiation in a particular type of way and sets this in relation to other uses (types/classes) of radiation, prior

authorisation focuses on the specific product and the risks its market entry might pose.

31. In the event of justification, the HPA-RPD will therefore need to conduct further tests on the safety toaster, making a risk assessment and using a prototype as the basis. This is important because the UK does not have a generic authorisation system at present to which to refer the toaster to, so any prior authorisation for the toaster needs to be conducted on a specific i.e. case-by-case basis.

## **B) The Applicant's Case for Justification**

### Justification Category Requested by Applicant

32. The applicant asked for the safety toaster to be classified under existing classes or types of practice no. 15 (Safety Devices – Use of ionising radiation in smoke and fire detectors and other safety instruments) in the Annex to Defra Guidance on the Justification Regulations 2004.
33. We made the applicant aware that if the safety toaster did not qualify under this existing category, we would check if it could qualify as a new practice or under a different existing category in the Annex. This would amount to a new justification decision.

### Benefits of the Safety Toaster practice listed by the applicant

34. In his request for justification, the applicant listed the following benefits for the safety toaster (verbatim):
- i) *Will never burn or blacken the toast*
  - ii) *Safety feature – will prevent accidental fires, injury or deaths caused by poorly controlled toasters*
  - iii) *Health benefits (no carcinogenic burnt toast)*
  - iv) *Will reduce accidental triggering of smoke alarms (a major problem in hospitals)\**
  - v) *Will eliminate the common annoyance of smoky kitchens*
  - vi) *Automatic time adjustment to cook or reheat any type of bread/bun/roll/bagel perfectly*
  - vii) *Gives a more convenient and relaxing user experience*

*\*Poorly controlled toasters not only cause inconvenience in homes but are a major problem in UK hospitals, hotels, student flats etc. whereby fire crews are called out automatically and residents/patients*

*are evacuated with the associated down-time, expense, inconvenience and trauma caused. The safety toaster will resolve this issue.*

35. The applicant also included 6 clear expressions of interest from professionals in the fields of NHS Trust Estate Management and Hospital Fire Safety over the safety toaster's ability to reduce unnecessary fire callouts and avoid subsequent hospital evacuations.

#### Applicant's View of Safety Toaster Detriments

36. In his request for justification, the applicant noted that exposure to radiation was reduced to an absolute minimum, explaining that:

*"The sensor is mounted upside-down inside a sheet steel air duct box capped with a perforated steel cover. This thoughtful design reduces any emissions, and therefore exposure levels, to virtually zero for safe use by consumers, in even in daily close proximity to the toaster (NRPB to confirm tests)".*

37. The applicant also highlighted that he had made provision for changes to environmental legislation, stating that:

*"Future legislation depicts that manufacturers will be obliged to accept end of life products, such as this safety toaster, for responsible disassembly and recycling where possible. The ionizing sensor is fully removable to comply with this requirement for responsible disposal.*

*The easily removable sensor also enables the user to easily upgrade, service or recycle this component to lengthen the life of the toaster".*

38. The DTI separately notes that the applicant in his request for a determination decision does not highlight alternate substances to radiation for the safety toaster.

39. The DTI also notes smoke detectors on ceilings or attached to alarm systems do not seem as accessible: given the potential ubiquitous appearance of the safety toaster in homes, we therefore ask whether the sheet steel air duct box, which houses the easily removable sensor, is or could be made child-tamper proof?

40. The DTI notes the HPA-RPD's potential radiation dosage report (dated 11 May 2005) states that, "The intention by the manufacturer is to ensure that the americium-241 particle sensor is

mounted in a tamper-proof chamber only accessible to the manufacturer using special tools”.

41. The DTI notes that the question of a tamper-proof chamber is an aspect of manufacture that will need quality assurance to satisfy prior authorisation and subsequent importation procedures.

## **Part III: The Consultation Outcome**

### **A) Consultees on Justification Category**

#### Any Outright Justification Ban for the Safety Toaster?

42. As mentioned earlier in the consultation report (see para 14), the DTI did not see the safety toaster as disqualified from consideration under a justification process: we understand the outright ban on the “deliberate addition of radioactive substances in the production of foodstuffs” does not forbid the use of radiation during production processes for food.

43. The FSA confirmed it had no objections to the development of the toaster.

#### Who ultimately determines the Justification Category?

44. The following specifically saw the justification category as a matter for the DTI to decide in its capacity as Justifying Authority for the safety toaster: HSE and EA.

45. The following deferred to justifying authorities: SEPA. Justifying authorities in the Concordat refer to UK Government Departments and the Devolved Administrations.

#### Any Devolved Administration Matters?

46. The DTI made clear that as the Justifying Authority for the safety toaster, it intended taking a view for the whole of the UK. The Justification Regulations 2004 (no.12) state that it is for the Secretary of State to make a determination on whether a practice belongs to an existing class or type of practices.

47. We specifically asked Devolved Administrations to highlight any reserved or transferred areas: none were registered.

48. The NAW confirmed that it was content with the handling of the application and did not have any issues.

#### Differences over Determining the Justification Category

49. Annex 3 of Defra Guidance (herewith known as “the Annex”) lists radiation practice types or classes that existed prior to May 13<sup>th</sup> 2000 and are therefore acceptable throughout the UK.

50. Consultees differed over which existing category the safety toaster might qualify under. There were 5 types of exchange on whether:

- Category 15 was possible;
- Category 10 was possible;
- A new category was required for the toaster;
- The toaster should not be justified;
- The safety toaster practice had existed previously, but was omitted from the Annex and therefore might de facto be considered acceptable.

#### Justification under Category 15?

51. Category 15 in the Annex (for previously existing and therefore acceptable radiation practices) is for “Safety Devices” and covers “use of ionising radiation in smoke and fire detectors and other safety instruments”.

52. FSA initially considered that the safety toaster could fall under category 15 because the smoke detector it included was there to prevent fires and control the level of chemicals in the toast: both purposes had safety benefits.

53. HSE thought that, “there could be a case for saying that the proposed use of smoke detectors in toasters is quite different from that in category 15. An installed smoke detector can remain in-situ for years and contains no serviceable parts, whereas the safety toaster would be portable and more likely to be dismantled during its life.”

54. ODPM disagreed: the safety toaster had much less likelihood of being opened up (if at all in many cases) compared to single point domestic smoke alarms, where Government policy encourages regular testing and maintenance by the user.

55. HPA-RPD’s view was that “the safety toaster does not fall within any of the currently defined existing practices. Although it contains the radioactive element of an ionisation chamber smoke detector, its objectives, use, benefits and possible detriments are very different to those of smoke detectors and associated safety devices.”

56. SEPA was unconvinced that the safety toaster fell under category 15 for several reasons:

- They understood this category “as relating to the detection of smoke from unplanned fires/accidents”;
- The smoke detector was integral to the safety toaster and should not be considered independently;
- The toaster was there to toast bread rather than act as a safety device;
- The device stopped the toasting process before smoke had been released, which raised doubts about being classified as a smoke detector.

57. In response to SEPA’s last distinction, ODPM noted that smoke detectors themselves did not detect smoke but a change in ionisation.

58. EA also thought that “the Safety Toaster is not a “safety device” or “safety instrument” within the meaning of Category 15 of the list of existing practices. The principal function of the Safety Toaster is to toast bread products, the safety benefits are incidental to the principal function”.

#### Justification under Category 10?

59. Category 10 in the Annex (for previously existing and therefore acceptable radiation practices) is for “Substance measurement and process control” and covers “use of sealed sources and x-ray generators for thickness gauging, density gauging, mass gauging, level gauging, flow measurement, borehole and well logging, control of pipeline crawlers” as well as “use of neutron sources for moisture gauging”.

60. SEPA thought this (i.e. no. 10) a more appropriate category than category 15 for the toaster because the smoke detector it included was there to control the toasting process (HSE took note of this position).

61. EA agreed: “it is considered that the use of the ICSD” (Ionising Chamber Smoke Detection) “in the Safety Toaster is effectively a form of “process control”, as referred to at Category 10” and recommended that the DTI consider a new category for justification if it did not think that the Safety Toaster fitted well into category 10.

62. HPA-RPD considered that the safety toaster “cannot be grouped into the substance measurement and process control practices” (i.e.

no. 10), “since these cover industrial applications and again have very different benefits and detriments.”

#### A new Justification Category?

63.EA questioned whether the safety toaster was a safety device and thereby an existing practice as foreseen in category 15, suggesting the toaster probably “should be assessed on its own merits as a new practice”.

#### No Justification Category?

64.DOENI stated that it “would not be happy to justify the use of a radioactive source in a toaster and would endorse the comments made by SEPA and EA”.

65.Their view was that “the toaster goes beyond the existing practice of using radioactive sources in smoke detectors – the latter are arguably safety devices”.

66.They argued that “while there may well be arguments that the toaster may prevent false alarms, and may prevent fires, the primary purpose of the toaster (and the marketing benefit which would be claimed) is that the toaster produces perfect toast every time and eliminates over toasting and actual burning.”

#### An existing Category but not yet in the Existing Practice Annex?

67.Dft noted that the safety toaster “was demonstrated prior to the justification regulations which could mean it is an existing class or type of practice”, i.e. should be included in the annex on accepted practices existing prior to 13<sup>th</sup> May 2000.

68.Dft also added that “moving from a demonstration basis to mass manufacture basis might place this in the realm of new and important information if the type of practice is deemed to be existing”.

69.At the request of the DTI, the applicant provided the following information on the history of the safety toaster:

- Approx. March 2000: Particle sensing safety toaster invented by applicant
- 5<sup>th</sup> June 2000: Patent filed under applicant’s employer’s name

- June 2000-June 2001: attempts to license technology to manufacturers failed (due to large employer sign-up fees)
- 30<sup>th</sup> January 2002: Patent assigned to applicant
- 6<sup>th</sup> March 2002: appeared on BBC's "Best Inventions"
- 25<sup>th</sup> August 2002: Finalist on BBC's "Tomorrow's World 2002 Awards"
- 28<sup>th</sup> August 2002: applicant leaves employer to pursue toaster project
- January 2004: applicant awarded SMART DTI grant to develop toaster
- December 2004: applicant completed "design and proven technology is feasible new sensing method for safer toasters"
- March 2005: Agreed manufacturing contract with leading UK brand (to be manufactured in China)

70. The DTI notes that whilst the applicant states the product was invented around March 2000, the patent was filed on 5<sup>th</sup> June 2000 and therefore after the cut-off date of 13<sup>th</sup> May 2000 for the Existing Practices Annex.

71. The DTI is not aware of any request was made by the applicant for justification of the safety toaster after 13 May 2000 and prior to the coming into force of the Justification Regulations 2004 when transitional arrangements applied.

72. Also the DTI is not aware that EA was consulted during the early design of the product (i.e. around March 2000) regarding the use of radiation wherever the applicant invented the safety toaster: neither the EA nor the applicant has indicated as such. Furthermore, the SBS East of England decision in November 2004 supporting the DTI SMART award does not mention this point.

73. Defra makes clear that the Annex of existing practices "is not exhaustive or authoritative" (Defra Guidance, para 33). Nevertheless, DTI felt it important to continue considering fully whether the safety toaster constituted an existing practice for reasons of transparency and overall consistency, as well as not least, because the product has a potentially wide market reach into private homes, public organisations and different types of businesses.

74. DTI further notes that the EA may well need to be involved from an early design stage, should the applicant develop future products

incorporating the use of radiation, or should it later become apparent in the event of justification and during prior authorisation, that the safety toaster requires modification to be safe/acceptable for the market.

## **B) Consultees on Safety Toaster Benefits**

### Significant reduction in false alarms – especially the Health Sector

75. With reference to ODPM's responsibility for fire safety, HSE noted potential benefits here (i.e. any reduction in false Health Sector alarms) might need to be quantified in terms of lives saved.
76. DOENI felt a reduction in false alarms should be classified as an economic benefit. They questioned the extent to which false alarms would result in deaths and injuries because fire appliances were elsewhere disposed, as well as querying how many false alarms could be put down to fires caused by toasters.
77. ODPM welcomed the safety toaster: false alarms from automatic fire detection systems accounted for a significant proportion of false calls to the fire service overall, whereby the health sector contributed the most with toasters as a major cause.
78. The DTI notes consultees did not provide final stats on lives saved, false callout numbers in the UK as a whole or the overall proportion of toaster incidents.
79. The DTI further notes that expressions of interest from NHS Estate professionals provided by the applicant in his determination request included various estimated statistics.
80. The DTI asks whether these figures could be verified and compiled (aggregated?) across the UK to give a clearer picture of the magnitude of false callouts and the degree to which toaster fires contribute.

### Health and Safety Benefits

81. DOENI's view was that "any health and safety case would need to be based on some demonstration that the toaster would reduce death and injury resulting from toaster fires....and possible health and safety benefits from a reduction in the ingestion of carcinogens

from burnt toast”. They saw little likelihood of reliable evidence on both fronts.

82. The FSA felt the applicant’s claim that the safety toaster “will encourage healthier (no more burnt carcinogenic toast)” was misleading, explaining that “the agency believes that a healthy diet contains lots of fruit and vegetables; is based on starchy foods such as wholegrain bread, pasta and rice; and is low in fat (especially saturated fat), salt and sugar. However, we do not give any consumer advice specifically related to burnt toast since we feel that the adverse/beneficial effects of burnt toast have not been fully assessed”.

83. The DTI notes that neither the applicant nor consultees provided specific statistics on the health implications of burnt toast.

### **C) Consultees on Safety Toaster Concerns or Detriments**

#### Environmental Impact of the Safety Toaster Practice

84. The EA was principally concerned with the “fate of these products once they become disused and the consequent radioactive waste management/disposal issues (landfill/incineration)”.

85. The JLG member of the DTI noted that “according to HPA-RPD guidelines, the use and disposal of modern commercially available smoke detectors does not hold any significant danger for the public and they can be disposed of through normal domestic use”.

86. The JLG member of the DTI added that according to HPA-RPD guidance, “smoke alarms have an exemption order from 1980 on their disposal from the Environment Agency since they have apparently such a minor impact in relation to their benefits”. It was likely that the same rules applied to the “commercially available off the shelf item” incorporated by the toaster.

87. EA did not wish to rule out new waste management issues - even if, the safety toaster were covered by existing smoke detector regulations (see para 90 ff. on “Radioactive Substances Act 1993 and Smoke Detector Exemption”).

### Health Detriment of the Safety Toaster Practice

88. ODPM noted that the luminous face of a wristwatch gave off more radiation than a single point smoke detector.
89. The FSA's main concern was any potential for radioactivity released from the smoke detector in-situ contaminating the toast. ODPM noted in discussion that foil could prevent any radiation spreading.

### Cumulative Radiation (storage, distribution, importation, transport)

90. ODPM noted that cumulative radiation through mass storage of the product could require a licence (see para 102 ff. on "Radioactive Substances Act 1993 and Smoke Detector Exemption").
91. DTI notes and makes the applicant aware that cumulative radiation considerations could well apply for importation and distribution including individual transport.

### Requests for formal Radioactivity Assessment

92. All parties understood and underlined the importance of the HPA-RPD's radiation dosage assessment to gauge the exposure risks during normal and accidental (e.g. fire) use of the safety toaster.
93. SEPA, with support from EA & DOENI, requested that any assessment include health detriment to the public resulting from the subsequent disposal of the device.
94. HSE asked for further information on the life expectancy of the toaster and subsequent implications for disposal because the use of a smoke detector "in a toaster will be quite different from that of a fixed installation smoke detector on a ceiling".
95. EA noted that "information on the working life and durability of AM-241 sources of this type is mainly derived from tests and experience of their use as smoke detectors fixed to the ceilings of buildings". Consequently, the EA pressed the applicant "for information on their survival in the proposed environment (i.e. daily thermal cycling in a hot air stream".
96. The HPA-RPD recommended it carry out a full justification assessment: "this entails the assessment of the benefits associated with its use and a comparison of these with the associated detriments. The detriments are primarily the potential radiation

dose received by the user, the magnitude of potential radiation doses following misuse or accident, and radiation doses associated with disposal.”

97. The DTI and HPA-RPD jointly recommended to the applicant to go ahead with an assessment of potential dosage from the HPA-RPD to help clarify radiation risks and whether additional tests would be necessary for the justification consultation process.

#### HPA-RPD’s Assessment of Potential Radiation Dosage

98. The DTI is grateful to the HPA-RPD for producing its report on the potential radiation dosage for the safety toaster.

99. For clarity, we note that the nomenclature “DETR” mentioned in the HPA-RPD’s report (pg. 4 ff.) in connection with the issue of radioactive disposal and the WEEE Directive should read Defra i.e. Department for Environment, Food and Rural Affairs.

100. The DTI emphasises that only if the findings in the HPA-RPD report mean that radiation dosage levels for the safety toaster under normal use and in accidents are acceptably consistent with or below levels expected for existing practices for smoke detectors, is it possible for the safety toaster in principle to fall under the smoke detector category.

101. We note that the HPA-RPD report focuses on domestic use for calculating radiation dosage and that kitchens for example in hospitals will have a different frequency of use: we see this as an issue for prior authorisation (including prototype testing and risk assessment from the HPA-RPD).

102. The DTI can confirm, in its capacity as Justifying Authority for the safety toaster, that the HPA-RPD submitted a written statement to this effect, addressed to it as the Justifying Authority as well as the safety toaster consultees and all members of the JLG.

### **D) Consultees on other/related Regulatory Issues**

#### Radioactive Substances Act 1993 and Smoke Detector Exemption

103. SEPA noted that “the keeping, use and disposal of radioactive substances on any premises which are used for the purposes of an undertaking are subject to regulation under the Radioactive Substances Act 1993 (RSA ’93)”. EA expanded that:

“Keeping or using” in this context includes retailers and other suppliers as well as kitchens associated with commercial and other undertakings”.

104. SEPA noted that premises with less than 500 smoke detectors did not require an authorisation, but was unsure whether the safety toaster qualified as a smoke detector and therefore whether it was eligible for the Exemption Order.

105. SEPA understood that the purpose of the safety toaster was “to make toast without creating smoke rather than to detect smoke” and highlighted that “this interpretation would mean non-domestic users such as hospitals, hotels and electronic equipment retailers would be subject to regulatory control under RSA’93”. Consequently, SEPA considered, “it may be necessary to amend an existing or introduce a new Radioactive Substances Exemption Order”.

106. EA asked for the regulatory burden to be considered if the Exemption Order did not apply, as well as (for completeness) the regulatory cost for any change to the scope of the Exemption Order to include the safety toaster.

107. EA further suggested that “a minor amendment to the Exemption Order, to include explicitly “other apparatus incorporating a smoke detector” as the best way to “ensure clarity and certainty for both the regulators and regulated”.

#### Ionising Radiations Regulations 1999 (IRR99) and the workplace

108. HSE noted that IRR99, which regulates exposure to radiation in the workplace, would apply “to the manufacture of such toasters in Great Britain, and their subsequent use and maintenance in a workplace, e.g. a works canteen, restroom etc.”

109. IRR99 relieves employers of the obligation to notify HSE that they are working with ionising radiation where less than 500 smoke detectors are installed or stored (and no other work with ionising radiation is carried out) through type approval arrangements.

110. However, HSE stressed that “as it is not yet certain if the safety toaster should be classified as a smoke detector or not – its purpose is to brown toast rather than detect smoke – HSE may

need to consider if type approval of the toaster may be necessary in due course”.

#### The Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR)

111. HSE noted that REPPIR would apply where 8000 or more ionisation smoke detectors are stored as this quantity may have the capability of producing a radiation emergency that could impact on members of the public. (REPPIR establishes a framework for the protection of the public through emergency preparedness for radiation accidents that have a potential off-site impact.)

#### Other Health and Safety Legislation

112. HSE noted: “other health and safety legislation that could impact includes the Health and Safety at Work etc. Act 1974 (section 6 duties on manufacturers, designers, importers etc to supply articles for use at work that are safe and without risks to health), the Provision and Use of Work Equipment Regulations 1998, and the Electricity at Work Regulations 1989 (inspection and testing of electrical equipment used at work)”.

#### WEEE Directive

113. EA raised concerns over “investigating the implications of the Waste Electrical and Electronic Equipment Directive” for the safety toaster.

#### Electrical Equipment (Safety) Regulations (SI 1994/3260)

114. DTI Standards and Technical Regulation advised that an electric toaster was required to be safe when placed on the market and would need to comply with SI 1994/3260.

#### Electromagnetic Compatibility Regulations (SI 1992/2372-SI 1994/3080)

115. Dependent on the design, DTI Standards and Technical Regulation advised, the safety toaster might also need to comply with the Electromagnetic Compatibility Regulations (SI 1992/2372) as amended by SI 1994/3080.

#### Importation Regulations

116. Dft noted that regulations may well differ, should the applicant import via another EU country rather than direct to the UK.

## **Part IV: The Justifying Authority's Response**

### **A) Possible Conflicts of Interest during Consultation**

#### Does SMART funding preclude DTI as the Justifying Authority?

117. The applicant noted at the end of his determination request that “*the safety toaster is a DTI SMART funded project (now completed) with the obligation to commercialise the technology as soon as possible*”.
118. DfT asked whether this presented a conflict of interest for the DTI acting as the Justifying Authority in this instance.
119. DTI can confirm that the decision to sponsor the safety toaster under SMART was made in November 2003 by the SBS East of England Development Agency (this ceased operations end of March 2005) under confidential and outside i.e. independent advice to which the DTI was not party.

#### Impartiality of JLG membership by DTI?

120. The JLG member provided by DTI comes from a separate i.e. non-related DTI unit to the DTI unit, which undertook the consultation process: this provides an internal check for transparency and impartiality purposes.

### **B) Justifying Authority's Conclusions**

#### Justifying Authority's initial view of the Safety Toaster Practice

121. When starting the formal consultation process, the DTI considered that the product had a wide range of benefits and a ready market.
122. In particular, the safety toaster appeared to offer a good case for justification under all main aspects – economic, health, safety and environmental – as a desirable consumer product (perfect toast); safety mechanism (prevents toaster fires); health appliance (prevents carcinogenic burn on toast) and for environmental protection purposes (prevents smoky atmospheres at work and in the home).

### Justifying Authority on Justification Category after Consultation

123. The DTI has considered carefully the arguments put forward by consultees on which category (classes or types) in the Annex of existing practices the safety toaster could (or should not) qualify under.
124. The DTI notes in particular Defra Guidance (para 26) stating that the EU BSS “refers to classes and types of practice, rather than simply to practices. This emphasises the underlying principle that justification is to be applied generically rather than at the level of individual uses of practice. There is no obvious intent in the Directive to differentiate between classes of practice and types of practice they may be widely or narrowly defined in particular cases”.
125. As formulated by legal advice on generic application of justification: *“In other words, the question to be asked is, “Is this type of activity justified?” rather than, “Is this particular example of this kind of activity justified?”*

### Justifying Authority on Benefits & Detriments after Consultation

126. EU BSS places a clear onus on Member States to keep exposure as low as feasible and within limits set for different groups of individuals (Article 6, paras 3 & 4): that is why a potential radiation dosage assessment conducted by the HPA-RPD was important for understanding the nature of exposure and thereby coming to a view on the order of magnitude for the benefits and detriments of the safety toaster, as well as how this compared with existing (and accepted) practices.
127. The DTI has also considered carefully the wider benefits and detriments, which the applicant and individual consultees raised (these are set out in detail in Part II and Part III of this consultation report).

### Justifying Authority’s Final Understanding of Justification for the Toaster

128. The DTI is not persuaded that on the arguments presented by consultees, the safety toaster falls into a new practice or that the application raises new and important evidence about its efficacy or consequences, which would entitle a review as to whether the practice can be justified (Justification Regulation 2004 no. 10).

129. The DTI considers that the product falls within an existing category for the purpose of no. 5 of the 2004 Justification Regulations for reasons set out here:

- i) Although the DTI accepts that placing a smoke detector in a toaster appears to be a novel use of such a product, the use of radiation in the smoke detector is no different than if it were attached on the ceiling or attached to an alarm system for instance: both of which qualify under existing practices;
- ii) The magnitude of exposure and benefits for the smoke detector remains the same whether on the ceiling or in the toaster because it is the smoke detector which provides the element of radiation risk;
- iii) The safety toaster incorporates a standard smoke detector, which is subject to the same environmental and health considerations as a standard smoke detector attached to the ceiling or an alarm system for instance – moreover the applicant has signalled willingness to work with authorities in anticipation of forthcoming disposal regulations;
- iv) The DTI accepts that the design of the safety toaster could compromise (as opposed to change) the accepted use of radiation and therefore makes clear that, whilst considering the practice of placing a smoke detector into a toaster as an existing practice in principle, the safety product must undergo rigorous examination through a specific authorisation process (that includes prototype testing and a risk assessment by the HPA-RPD) before being allowed entry to the market;
- v) The DTI notes with thanks that consultees raised many important concerns around the integrity of the product and its suitability for the market: the DTI understands these need to be satisfied in the event of prior authorisation rather than relating to the more immediate process of justification which determines broad categories of accepted practices and not individual examples of a particular type of practice;

- vi) The DTI notes that the UK does not operate a generic system of prior authorisation, and, even if it did, it is our view that the safety toaster would still need to undergo specific prior authorisation because, as far as we are aware, there are no existing products on the market with which to make clear comparisons over the product's integrity in 2 respects: the first being any compromise of justified use of radiation (see iv) above); the second being any breach in existing standards and regulations.

130. On the basis of this understanding, the DTI has therefore determined - given the official confirmation received from the HPA-RPD on the interpretation of its potential radiation dosage findings (as set out earlier in this consultation report) - that the smoke detector used in the safety toaster falls under the existing practice type or class for smoke detectors (no. 15 in the Annex to Defra Guidance).

131. On the various safety toaster interpretations raised by consultees, the DTI makes the following observations:

- i) In practice, smoke detectors detect “smoke” (or more precisely, according to the ODPM, a change in ionisation i.e. the number of particulates in the air) – irrespective of whether the fire is planned or not.
- ii) It can equally be argued that the purpose of the safety toaster is to toast bread safely (as its name implies), rather than to simply toast in a pleasing (i.e. perfect) manner for the consumer: the emphasis by the applicant on potential reduction in fire safety callouts would bear this out (albeit no final stats have emerged to hand during this consultation on the scale of false callouts in the UK and the proportion of fires in toasters etc.).

#### Scope and Applicability of the Justifying Authority's Decision

132. The DTI notes that under no. 12 of the Justification Regulations 2004, where the Secretary of State makes a determination that the practice in question belongs to an existing type or class of practice, no secondary legislation (i.e. Statutory Instrument) is required.

133. Defra Guidance (para 36) notes that, “Functions performed by the Justifying Authority in Scotland, Northern Ireland or Wales are exercised only in respect of their own countries whilst those performed by the Secretary of State may be applied to the whole of the UK. For example, determinations under Regulation 12”.

134. The DTI notes that it is for the Secretary of State to make a determination on whether a practice belongs to an existing category (class/type) and that Devolved Administrations must be consulted in advance of such a determination, but are not part of the final determination process under Regulation 12. This report makes clear that the Justifying Authority consulted fully with Devolved Administrations and that it notes for completeness that during consultation no reserved or transferred areas were registered by Devolved Administrations.

#### Implementation of the Justifying Authority’s Decision

135. The form of determination is simple. Regulation 14 (3) of the Justification Regulations 2004 states that it must be in writing and can, with the agreement of the applicant, be communicated to them electronically (regulation 14 (4)). Regulations 14 (5) and (6) require the determination to be notified in various official gazettes “forthwith”.

#### Justifying Authority’s Recommendations to Applicant Post-Justification

136. The DTI recommends that the applicant consider all the issues highlighted in the consultation report and seeks advice as appropriate from those involved in the consultation, specifically on: what benefits can be claimed; the environmental impact and any potential health detriment during disposal; cumulative radiation concerns; the wider regulatory environment and the specific applicability of individual pieces of regulation.

137. For clarity, the DTI emphasises to the applicant, that justification is a generic application procedure on the use of radiation in principle: specific prior authorisation, especially given that the safety toaster is a novel product, is essential before the product can enter the market.

138. The DTI understands, in discussion with the HPA-RPD, that there are 2 aspects to prototype testing for a novel product: firstly, determining a standard with which the product needs to confirm; secondly, testing that product’s ability to meet that standard during

(mis)use – quality assurance will be an important element of manufacture and for importation. Developing an objective standard and then testing the product against it may take several months.

139. The DTI notes that specific prior authorisation for the safety toaster will include prototype testing and a risk assessment from the HPA-RPD, as well as the need to comply with the wider regulatory framework as highlighted by the responses of the consultees.

#### Justifying Authority's Request to Consultees Post-Justification

140. The DTI is grateful for the issues raised by consultees and asks that they continue their help during the prior authorisation stage.

## **Part V: Drawing Justification to a close**

### **A) Formal Notification to the JLG**

141. This consultation report was the basis for informing the JLG of the determination proposal after consultation by the Justifying Authority that the Safety Toaster belongs to an existing group of ionising radiation practices and therefore accepted throughout the UK.

142. We asked the JLG to consider whether the justification determination proposed in this report is consistent with an approach that would be taken across UK Government and applicable throughout the UK. JLG members agreed.

### **B) Public Availability of the Justification Outcome**

#### Transparency, Accountability and UK-wide Consistency

143. The DTI will inform the applicant and publish the consultation report in accordance with the Justification Regulations 2004 now that members of the JLG have confirmed the wider consistency and applicability of the Justifying Authority's approach.

#### Sharing Information and Confidentiality

144. The Concordat makes clear that a successful justification process relies on close co-operation and that information supplied by individual parties is subject to appropriate safeguards.

#### Request to Consultees on what's made public

145. In response to our request, consultees indicated they agreed that attributions for individual contributions could remain in the consultation report when it becomes available to the public.

### **C) Concluding Remarks and Thanks to Consultees**

146. The DTI would like to thank all consultees for their detailed and wide-ranging contributions: these have helped clarify which issues the applicant must address not only to ensure acceptable use of radiation in principle but, importantly, to ensure acceptable product safety compliance prior to market entry.