

**Statement by the Justifying Authority on its proposed
Justification Determination for the Safety Toaster
Application**

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

Dated 22 June 2005

Determination Decision

The DTI, as the Justifying Authority, is in a position to determine that the safety toaster falls under the existing practice type or class for smoke detectors: no. 15 in Annex 3 to Defra Guidance on Justification of Practices Involving Ionising Radiation Regulations 2004 - SI 2004 No. 1769 (herewith Justification Regulations 2004).

The safety toaster can therefore be determined as belonging to an existing practice in principle, subject to confirmed and public approval by the DTI's SoS.

The Determination Rationale is set out below and based on the Consultation Report that follows it.

Determination Rationale

Overall Consultation Outcome

The DTI was able to reach this determination proposal on the basis of an extensive mandatory consultation foreseen in Justification Regulations 2004.

The Consultation Report sets out in full the issues raised by all during consultation, together with the rationale for and the scope of the proposed justification determination.

Members of the Justification Liaison Group (JLG), tasked to oversee consistency and co-operation across government on questions of justification, have confirmed the proposed determination and its rationale is consistent with an approach that would be taken across the UK government.

Consultees on the safety toaster application for justification have also confirmed that the Consultation Report accurately reflects their views.

The HPA-RPD calculated similar radiation dosage values during normal use and accidents for the safety toaster to those for justified smoke detectors. RPD refers to the Radiation Protection Division of the Health Protection Agency (HPA): it used to be called the NRPB (National Radiological Protection Board).

Eligibility for consideration under Justification Regulations 2004

The DTI, as the Justifying Authority, considers that the safety toaster is eligible for consideration under the Justification Regulations 2004.

It understands the outright ban on the “deliberate addition of radioactive substances in the production of foodstuffs” in the EU Council Directive 96/29 Euratom 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. Lawyers have confirmed this view.

Generic Application of Justification

On the issue of wider consistency across government, the DTI notes that justification is to be applied generically, so the question is whether a type of activity is justified (i.e. using radiation to “detect smoke” or more accurately changes in ionisation current through airborne particulates), rather than whether a particular example of this kind of activity is justified (i.e. the safety toaster).

Members of the JLG (Justification Liaison Group) have confirmed this approach.

Dual Justification Rationale for Existing Practice Determination

Although the DTI accepts that placing a smoke detector in a toaster appears to be a novel use of such a product, the DTI concluded that

- i) such use of radiation in a smoke detector,
- ii) and any balance of benefits and detriments of such a use,

is no different than if the smoke detector were attached on the ceiling or attached to an alarm system for instance: both of which qualify under existing practices.

Importantly, the safety toaster incorporates a smoke detector as a sealed unit. The way the smoke detector uses radiation and the balance of benefits and detriments of using radiation in that way stay broadly the same. As smoke detectors belong to an existing practice in principle - that is to say fall into an existing class or type of practice as listed in the Defra Ionising Radiation annex - the safety toaster can also be determined as belonging to an existing practice in principle.

Proposed Determination supported by Justified Dosage Comparability
Importantly, the proposed determination of the safety toaster as an existing practice is supported by written confirmation from the HPA-RPD to the Justifying Authority (copied to consultees and members of the JLG), that the values calculated in its radiation dosage assessment report for the smoke detector in the safety toaster are similar to those of a smoke detector attached for instance to the ceiling, and therefore these safety toaster values fall within the accepted margins of values for existing practices for smoke detectors in category 15 of Annex 3 of Defra Guidance for the Justification Regulations 2004.

Separation of Justification and Prior Authorisation Issues

The Consultation Report draws an important distinction between what is required to come to a view on justification, i.e. whether the use of radiation is acceptable in principle, and what falls into the arena of prior authorisation i.e. where regulations and concerns may need to be satisfied before the product is acceptable (deemed safe) and therefore ready for the market.

Rigorous Specific Prior Authorisation Process needed

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 determining that this use falls within an existing class and therefore accepting that the practice of placing a smoke detector into a toaster is determined as belonging to 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.

Novel Product's Integrity and Acceptability to be tested

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, the safety toaster is a novel product. This means there are no existing products on the market with which to make clear comparisons over the product's integrity and acceptability in 2 respects: the first being any compromise of justified use of radiation; the second being any breach in existing standards and regulations.

Specific Justification and Specific Prior Authorisation needed

The DTI emphasises that, the safety toaster is treated on a specific case basis for the present purposes of justification and subsequent prior authorisation because the safety toaster is a novel product. This means the

prospect of future procedures need not delay the completion of the justification procedure and any progress on specific prior authorisation for this safety toaster.

Type Approvals and Generic Prior Authorisation Possibilities

The DTI understands that the safety toaster may, in principle, help set up type approvals for similar designs in future, as part of the process for developing a generic system of prior authorisation in the UK - in particular, this could well prove useful when developing generic prior authorisation procedures for consumer products.