



Authorisation of watches containing Tritium





Regulatory Context

- **EURATOM Directive 96/29** : “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” (Article 6.5).
- **French Code of Public Health** : article R. 1333-2 of the PHC prohibits the intentional addition of radionuclides in consumer goods.
- French regulations allows for the **possibility of derogation** concerning this ban (Article R. 1333-4).
 - Dispensations to this prohibition may be granted by the Minister for Health if they are justified by the benefits that they provide compared with health risks that they may cause.
 - The following types of material are not concerned by this possibility of dispensation : foodstuffs, materials placed in contact with foodstuffs and water intended for human consumption, toys, personal ornaments and cosmetics.



Questions posed

- Assuming that article 6.5 of Directive 96/29 has been transposed into your national regulatory framework, **does your national legislation include the possibility of marketing consumer goods concerned by the deliberate addition of radioactive substances?** If YES, please specify the regulation including the specific treatment for watches in your country, if any.
- If there is any possibility of marketing such consumer goods, **which is the competent body for the authorization of the marketing of these products** and what is the role of the radiation protection authority?
- If the specific watch traser® H3 is marketed in your country, **which have been the scientific and regulatory basis for authorization.** In particular, **does your national legislation (or position) consider that a watch is a personal ornament?** If No, please explain why?

Follow-up actions

- Information meeting with mb-microtec and French Department of Health on November 2011
 - The « personal ornament » issue is closely related with the use of the watch. Until now, **french position was to consider all watches as personal ornaments**. But some uses made with the watches shall now make us change our opinion (extreme conditions).
 - For the moment, no application for authorisation sent by mb-microtec®.
 - In this case, the justification aspect will be examined carefully. In fact, **alternative solutions exist** (photo-luminescent paint : Superluminova®) but features are not fully the same, in particular concerning the performance length.
 - The **end life of watches** still remain uncertain (no return planned by the manufacturer)

