



Clarify the Scope

Feedback from the European Institute for Food Law on Reference Ares(2017)4196327 regarding Directives 1999/2/EC and 1999/3/EC

Irradiation is a taboo technology. Any practice coming within the scope of the Directive is de facto prohibited. The scope of the Directive is overbroad. By consequence it pushes more technologies from the market than can be justified on the basis of risk analysis. It is vital that only those practices are within the scope of the Directive that relate to the purpose of the Directive. The core purpose is to protect consumers from radioactivity. The European Institute for Food Law advocates improved delineation of scope of the Directive.

The European Institute for Food Law is an independent non-profit foundation based in the Netherlands, dedicated to the advancement of the level of expertise in food law and regulatory compliance.

As every girl/boy-scout and survivalist knows, exposure of water to direct sunlight (by hanging it in a clear plastic bottle in the Sun) significantly increases the safety of the water as the rays of sunlight (the UV in particular) kill off most of the bugs.¹ This is just one example of a practice that is illegal under the Directive. To some, albeit minor, extent sunlight is ionising. Therefore this way of manufacturing safer drinking water is within the scope of the Directive (Art. 1). No-one would dream of requesting authorisation of such practice, not only because the costs are prohibitive for girl/boy-scouts, but also because exposing to sunlight is not one of the three sources of irradiation that can be authorised under the directive (Art. 3(2) in connection to Annex II).

When reading this example, one may shrug thinking it is obvious that such practice is not *intended* to be within the scope of the Directive and that most of the ionising radiation anyhow is filtered out by but the Earth's atmosphere and that most of the effect is due to photochemistry and heat, rather than ionisation. However, this is precisely the problem. The scope of the Directive is not clearly defined. The wording of the directive ('ionising radiation' without any further qualification) brings practices within its scope that should not be there. Many applications are currently on hold in the EU or not even researched because they would come within the overbroad scope of the Directive. The main source of overbroadness of the scope is the absence of any qualification to the concept of ionisation. A clear and measurable cut-off limit well above zero either in terms of ionisation or of energy or both is required.

Food safety should not be taken lightly. Human lives are at stake. From listeria alone annually between 100 and 300 people die in the EU (according to EFSA). This number could be lower if EU procedures would not block technologies for political reasons that have been found effective and safe by science including EFSA – irradiation is not the only example, for a random other example think of the use of bacteriophages.

The European Institute for Food Law endorses the principle laid down in Article 6 of Regulation (EC) 178/2002 that food law should be based on risk analysis (i.e. on science). The Institute is deeply concerned about the functioning of the Standing Committee for Plants, Animals, Food and Feed which seems to underestimate the importance of food safety and seems to be functioning in a too political way to be able to truly follow the lead of science.

¹ Indeed this method is so well known that it is even mentioned in fiction literature: see Terry Pratchett and Stephen Baxter, *The Long Utopia*, Harper 2015, p. 55 (in the eBook version).



The EHEC crisis could have been prevented if the surface of the seeds used for sprouting would have been treated with low energy electron beams, sufficiently gentle not to affect their germination. However, such treatment cannot be allowed under the Directive. In Art. 3 in conjunction to Annex III(1) the Directive requires a ratio of D_{max}/D_{min} not exceeding 3. Such ratio can only be achieved if irradiation is through-and-through. Non-penetrating treatment gives a factor zero for the D_{min} . The ratio is then ∞ . This is infinitively higher than 3 and thus illegal if we take the text of the Directive at face value.

What needs to be done? The purpose of the Directive should be to protect consumers from radioactivity (and to ensure effectiveness of treatment). Radioactivity can be at stake if radioactive sources of radiation are used or high energy electron beams and if the radiation enters the food. In situations where it can be known upfront that the risk of radioactivity is not involved, the Directive should not apply. We already find in literature that UV is frequently considered not to be ionising.² This outcome may be satisfying, but how the reasoning goes in the face of the wording of the Directive, is mystifying. The scope of the Directive must be clarified and limited to those applications that actually need to be captured. One way of doing this would be to make the assumption that the radiation goes through-and-through explicit³ and make it part of the scope of the Directive, and further to introduce not only an upper energy limit (10 MeV), but also a lower energy limit, which should be part of the scope of the Directive (i.e. radiation below an undisputable safe limit, for example 1 or 0.1 MeV, should be placed outside the scope). This clarification of the scope of the Directive should ideally be achieved through a change of the wording of the Directive (Art. 1). A fast track alternative (whether or not awaiting legislative changes) could be interpretation of the scope through a Commission guidance document.

As to the dosimetry requirement (in Annex III), the European Institute for Food Law recommends harmonisation towards the Codex Alimentarius (i.e. abolishment of the requirement). The concept of dosimetry is no longer used in the Codex General Standard for Irradiated Food and the Code of Practice for Radiation processing of Food because it is not considered useful for food legislators and food business. In the EU, EFSA is of the same opinion.⁴ Alternatively, surface treatment could explicitly be taken out of the scope of the Directive.

If food safety is key, possibilities to increase food safety should only be subjected to market access barriers that are shown by risk analysis to be required to protect the life or health of consumers.

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Maria Antonietta Ruggiero MSc (researcher)

Prof. dr. B.M.J. (Bernd) van der Meulen (director)

² For a random example, see: Shama G. (2007). UV Disinfection In The Food Industry. [online] Available at: <https://www.cemag.us/article/2007/04/uv-disinfection-food-industry> [Accessed 3 October 2017].

³ The Dutch language version of the Directive uses wording 'doorstraling' that indeed does imply this. The German version uses the opposite wording 'Bestrahlung', not 'Durchstrahlung'. Other language versions, use words that could mean both ('irradiation', 'Irradiation'). One could consider internal harmonisation of the text of the Directive towards the Dutch language version.

⁴ See: EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on the Chemical Safety of Food Irradiation. EFSA Journal 2011;9(4):1930. doi:10.2903/j.efsa.2011.1930, p.2.