Control of food irradiation: A challenge to authorities

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The public demands clear labelling of irradiated food, and it is the obligation of food control authorities to enforce labelling and verify declarations. *Post factum* identification of irradiated foods is a valuable tool for these authorities. However, it is not clear what the label 'irradiated' tells us about the correct or legal dose, nor is it always easy to perceive the practical implications of the regulations. Although methods to verify whether or not a particular food has been irradiated are accumulating, identification alone does not prove adherence to legal dose limits. For technical reasons, radiation processing always results in a dose range within the product, while it is important that the minimum effective dose is applied and that any upper dose limit is respected. Only reliable inspection of records available at the irradiation facility can reveal this range and the statistical dose distribution and, thus, render labelling meaningful.

The idea of using the bactericidal action of ionizing radiation to extend the shelf life of food is nearly 100 years old. However, only the availability of powerful radiation sources with a potentially high throughput has made industrial realization of this idea possible. Now, after half a century of intense and comprehensive research, the innocuity and wholesomeness of radiation processing of food have been proven, the economic benefits are established, and governments are beginning to realize the contribution this technology can make towards ensuring a safe food supply. Beneficial applications include extension of the shelf life, the elimination of pathogenic organisms and microorganisms, the eradication of insects (for quarantine purposes), and product improvement. The acceptance of food irradiation by consumers is still controversial. However, the main topic of importance for governments and food control authorities should be the development of reliable methods to control use of this technique.

Ionizing radiation is not significantly different from other food preservation processes in causing some measurable changes and, at the same time, some beneficial effects. However, evidence that such measurable changes have occurred is not proof that the treatment has been adequate and effective. In the case of food irradiation, *post factum* identification methods are very helpful for the enforcement of labelling, but most cannot prove that pathogenic microorganisms have been eliminated or that insects have been eradicated (although it would be possible to enumerate surviving microorganisms or to use probes to detect viable and proliferating insects). In general, evidence of correct processing can only be obtained from the log books of irradiation facilities. Only such log books document the fluctuations in all process parameters; this is true of any process. In radiation processing, dose fluctuations are caused by variations in the density and composition of the material being processed, variations in the shape and size of any packaging, and variations in the orientation of the product and packaging relative to the radiation source. In addition, the technology is inherently incapable of applying a strictly homogeneous dose to the treated goods. Limited penetration of radiation and the progressive absorption of energy during the passage of radiation through the goods cause a range of doses in the product throughout a particular batch. Of course, there are technological approaches available to reduce the extent of this range, but such measures are costly. Again, these observations apply to any technical process; for example, heat sterilization in a retort will result in overcooking of some portion of the product in order to achieve the desired effect in the areas of minimum heating. This general property of any engineered process has consequences for the development of appropriate regulations and their enforcement through control and inspection.

The argument

Over two decades the lack of *post factum* methods for the identification of irradiated food served as an argument deterring the practical introduction and legal clearance of this new technology. At present, with reliable routine methods for the detection of radiation-processed foods available to the authorities -- at least for the most promising applications[1,2] – the responsible officials are not ready to carry out their jobs. After the licensing of several food items for radiation processing at various dose levels and for many different purposes in a growing number of countries, it is not *post factum* identification that counts or is needed. *Post factum* methods are only suitable for controlling food that is not allowed to be radiation-processed, although they may help to enforce the labelling of radiation-processed food and to enhance the confidence of the public in the inspection system. Furthermore, clearances in most cases define dose limits that are in a range unsuitable for direct dose measurement. The evidence of correct radiation processing is available exclusively from the log books of radiation processing facilities. This is not an argument against the use of *post factum* methods for the prosecution of illegal practices, but it is a challenge for

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authorities to be prepared for a growing and international market in irradiated foods. It is an argument against concentrating all efforts in the development of *post factum* methods and thus merely pleasing the public, and it is an argument for governments and authorities to face their obligations to provide their people with a safe supply of food – including food processed by ionizing radiation within the legal dose limits – and an inspection system that inspires consumer confidence.

The concept of 'overall average dose'

The conclusion of the FAO/IAEA/WHO (Food and Agriculture Organization / International Atomic Energy Agency / World Health Organization) Joint Expert Committee on Food Irradiation (JECFI) that any food irradiated up to an overall average dose of 10 kGy is safe[3] was based on toxicological considerations. In the dose range of interest (at least up to 15 kGy) chemical studies have proven that all effects of irradiation are linearly proportional to the dose – and thus that it is possible to interpolate and extrapolate the results. For example, on the basis of linear extrapolation of the results of laboratory studies and feeding tests on chicken irradiated at a dose level of 7 kGy, chicken irradiation at doses up to 10 kGy is considered to be safe. The supposition of linear interpolation and extrapolation has been validated within various food groups and classes and, finally, applied to all foods.

In order to estimate the toxicological implications of consuming irradiated foods, it had to be assumed that the occasional ingestion of some food irradiated at higher dose as a result of the inevitable random fluctuations would be compensated for during the next meal by the consumption of some food with a randomly lower dose. Thus, the ingestion of hypothetical radiolytic compounds would finally level out at some average value, and the total amount of hypothetical radiolytic compounds consumed might be estimated from some grand average, over an extended period of time, of the total intake of food irradiated at several appropriate dose levels. Thus, the consumption of a very small amount of some ingredient irradiated at elevated doses (e.g. spices, which play only a minor role in relation to the total volume of the diet) would be compensated for by the consumption of other foods irradiated at moderate doses (i.e. the main diet). Such considerations led to the irradiation of spices at up to 30 kGy being permitted in the USA[4].

Therefore, 'overall' in this toxicological context really implies 'all' – that is to say, 'all the food' consumed during the period of evaluation. The physical quantity 'overall average dose', therefore, is a highly theoretical conception and designates an average dose calculated 'over all' the consumed food; it is not at all suitable for a real physical measurement.

During their discussions, the JECFI realized that the then newly created notion of 'overall average dose' would necessarily imply that some portion of the treated food receives a dose higher than the average. For technological reasons and from available information about existing facilities for food irradiation, it was assumed that this higher dose would be ~50% above the average dose[3]. However, no quantification was established by the JECFI.

The concept of Codex Alimentarius

On the basis of the JECFI's findings, the Codex Alimentarius had to develop a Standard[5] for foods processed by ionizing radiation. For this purpose the JECFI findings had to be refined and amended (see Annex A of the Code of Practice[5]): the limiting maximum dose was defined to allow less than 2.5% of the product to receive a dose above 15 kGy (which is 50% above the 'overall average' dose of 10 kGy as defined by the JECFI). This definition is close to the usual approach used in technical regulations for limiting values.

For a very theoretical consideration of toxicological arguments, assume that the mean dose is ≤10 kGy. A combination of 10 kGy mean dose and ≤2.5% above 15 kGy is the most critical combination. Lowering the mean dose to <10 kGy but retaining a maximum dose of 2.5% above 15 kGy would be more on the safe side for the purposes of toxicological modelling. However, the resultant widening of the underlying statistical frequency distribution would necessarily result in a correspondingly lower minimum dose limit, approaching zero treatment (see Fig. 1). This means that some portion of the mass of product would receive less than the minimum effective dose determined in laboratory and commercial-scale experiments and, thus, that the treatment would fail to achieve the beneficial effects of radiation processing. Consequently, this is not a realistic situation, and would be in contradiction to 'good irradiation practice', which requires that the dose range be as narrow as is technically feasible.

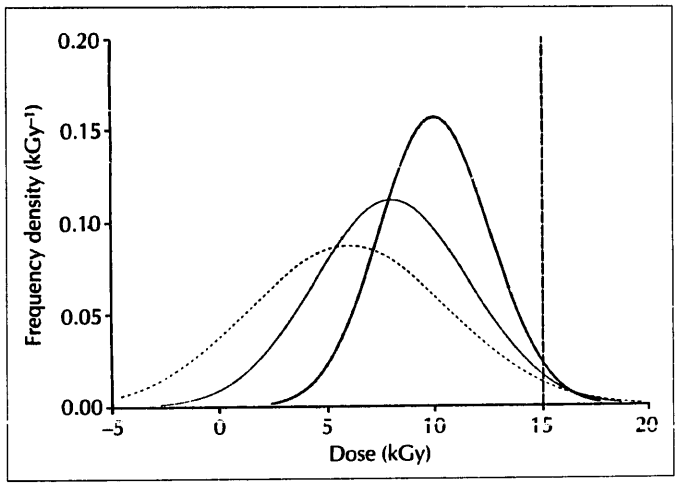

Fig. 1

The concept of 'overall average dose' as defined by Codex Alimentarius: for a mean dose of 10 kGy, 2.5% of the irradiated mass may receive a dose of >15 kGy (thick line; the area under the curve above 15 kGy represents 2.5%); use of a lower mean dose (thin and dashed lines) while maintaining a fixed 2.5% portion above the 15 kGy limit results in very wide frequency density distributions.

Codex Alimentarius did not give any advice as to whether average dose values or maximum and minimum dose values should be used in regulations. Some recommendations for maximum doses, however, were taken from the evidence laid down before the JECFI (Annex B of the Code of Practice[5]). At that time, it was considered to be worthwhile to preserve this information, which had been incorporated into the Standard of 1979; however, Codex Alimentarius did not foresee that this information might be misunderstood and be directly transferred into regulations.

Codex Alimentarius developed the concept that the 'overall average dose' can be measured only by using a large enough number of dose meters distributed strategically and at random throughout the total mass under consideration. It also indicated that determination of the mean of the minimum and maximum doses is a reasonable substitute for measurement of the 'overall average dose' where the 'overall' measurement is too difficult or, for any reason, impossible. In most cases, information about the minimum and maximum doses received by the product is easily available; thus, the mean of minimum and maximum doses would give the best available estimate of the average of the treatment and thus of the 'overall average dose'. Consequently, it would be prudent to use this concept.

The concepts used in regulations

The type of clearance granted for radiation processing of food varies considerably from regulation to regulation. In some cases a broad class is denominated, such as 'fruit' or 'dried fruit'; in other cases a single item is listed, such as 'strawberry' or 'parts of frog'. In addition, a complete enumeration of the members of a class may be used, such as 'onion, garlic and shallot' (see Table 1). From a scientific viewpoint it is advisable to use the concept of groups based on similarity rather than an item-by-item approach. The optimum radiation treatment for all members of such a group would be in a similar range of doses, and their chemical similarity would substantiate use of the 'overall' concept, as they would be expected to produce similar radiolytic products. Furthermore, regulations need to specify quantities that are suitable for use in controlling the process under practical industrial conditions. Only a few countries restrict their regulations wisely by setting limits for maximum dose only. It is possible to regulate radiation processing through the regulation of average doses only as long as the legal average values are well above the minimum effective dose for the particular application. The new regulations in The Netherlands do not come up with a practical solution to this problem, but do leave room for the possibility of some technical solution in practice, and do not refer to the incorrect terminology of 'overall average dose'. For example, the average absorbed irradiation dose for chicken is regulated at 7 kGy, and a maximum dose of 1.5 times the mean dose (10.5 kGy) is allowed; assuming that the frequency distribution of doses is symmetrical, the minimum dose would be 4.5 kGy, which provides a wide enough range of allowable doses to permit the operator of the facility to adjust the irradiation parameters in a reasonable manner and to achieve an effective treatment.

Governments and authorities are usually very cautious about accepting new technologies. For this reason, in most countries at least, the clearances for food irradiation were initially defined on an item-by-item basis. Compared to this worldwide situation, regulations in member states of the European Community (EC) are very progressive in regulating groups of food. The real problem lies in the kind and nature of the dose quantities specified in the regulations (see Table 1). As long as a clearance is general – i.e. for any food – it is appropriate to regulate the 'overall average dose' and to use only one value, namely 10 kGy, as in the Codex Alimentarius Standard or in the JECFI findings. This quantity defines a dose up to which radiation processing is considered wholesome. The JECFI found that any food processed up to 10 kGy is safe from a toxicological viewpoint. Specifying lower values for this quantity would be in contradiction to these JECFI findings on wholesomeness. For this reason, the regulation in the UK and the proposed directive of the EC are not appropriate. France and The Netherlands avoid such problems by specifying maximum or average doses; at the same time The Netherlands provides for the practical requirements of process control in setting maximum dose limits relative to average doses. In the UK, although the wrong quantity is used for the 'overall average dose', maximum dose limits are specified that are in accordance with good irradiation practice. The EC has not yet considered setting dose limits. Consequently, a mixture of appropriate and inappropriate concepts is being used. However, at present the main drawback of food irradiation remains the reluctance of food producers and manufacturers to use this technology.

Table 1. Irradiation regulations in EC member states compared with international standards[a]

Organization/ member state	Type of clearance	Quantity	Limits
France	Group and item	Maximum dose	Maximum
The Netherlands	Group	Average absorbed irradiation dose (D_{ave})	$D_{max} \leq 1.5D_{ave}$
UK	Group	Overall average dose (D_{oa})	$D_{max} \leq 3D_{min}$ $D_{max} \leq 1.5D_{oa}$ per batch
EC	Group	Overall average Dose (D_{oa})	Not specified
Codex Alimentarius	General	Overall average dose (D_{oa}) = 10 kGy	97.5% of doses $\leq 1.5D_{oa}$
JECFI	General	Overall average dose (D_{oa}) = 10 kGy	$D_{max} \leq 1.5D_{oa}$

[a] Adapted from Ref. 6

The 'self-controlling' nature of radiation processing

It is well understood and accepted generally that too high a dose would impair the quality of the radiation-processed food – as is the case with most overtreatments. As a consequence, neither the owner of a food nor the contractor for radiation processing has any interest in deliberately applying unnecessarily high doses. It is also obvious that higher doses result in higher processing costs, and that economics therefore demand the use of as low a dose as possible. On the other hand, too low a dose will necessarily result in failure to achieve the desired effect, and the costs of radiation processing will then not be balanced by the benefits of the application. As in other economic situations, the process of the application of radiation to food has to be designed to meet two separate requirements: the radiation dose throughout the treated consignment must be between the lower and upper technological limits for the particular food, and the intended purpose must be fulfilled.

It is evident that the toxicological concepts of the JECFI and the technological approach of the radiation processing industry have not been taken into consideration in an appropriate manner by most regulators. As a result, it is now up to food inspectors to decide whether legal requirements that in principle cannot be fulfilled are being met in the technical practice of radiation processing.

Radiation quantities used in process control

Irradiation facilities are prepared to meet the requirements of their customers for an effective treatment. Because of the self-controlling nature of the process, the adherence to technologically limiting minimum and maximum values of absorbed dose for a particular food and purpose is in the interest of both the contractor and the operator of the irradiation facility. In order to be able to settle disputes of liability, the operator of the irradiation facility will have reliable and probative evidence that the goods received the correct dose. At the same time, evidence is laid down at the irradiation facility that any specified, legal limit has been observed. Such evidence cannot be produced by any *post factum* method of identifying an irradiation treatment, even now, when the most advanced methods allow the estimation of a dose range.

In the USA, for very specific reasons, an exceptional situation was created for the radiation processing of chicken. Once the minimum dose for the reliable elimination of pathogenic microorganisms was set at 1.5 kGy, the allowable maximum dose was as a precaution set at 3 kGy (this is not the place to discuss the justification of the assumptions and the microbiological evidence behind them). The main practical problem of how to deliver these absolute maximum and minimum doses has been left with the operator of the irradiation facility. The US Food and Drug Administration (FDA) and Food Safety and Inspection Services (FSIS) have already expressed their desire to be present during radiation processing. As long as the statistical nature of measurement and processing is acknowledged, neither minimum nor maximum dose values would be an absolute barrier; it would be tolerable for a minute portion of the irradiated product mass to fall outside these limits. Of course, the tight end is the lower dose limit, as there is a risk that the treatment will fail to achieve the desired effect. If the statistical nature of the problem is acknowledged, a technical solution to the problem is possible and the risk of occurrence of undertreatment can be reduced virtually to zero (to 0.05%; see Fig. 2). The quotient of maximum to minimum doses in radiation-processed products is usually in the range 2–3; in this special situation the quotient has to be reduced to less than 2 by the use of additional and costly measures (e.g. loading the carriers to only half capacity). The burden of these measures would largely fall on the operator of the irradiation facility.

However, none of the existing regulations provide for an approach that takes the statistical nature of the problem into account. If authorities insist on absolute limits the operator is forced to use the statistical evidence to set the facility parameters in such a way that the resulting dose distribution is outside the critical range, for instance by applying a 'three times sigma' concept (Fig. 3): the irradiation parameter (e.g. conveyor speed or beam power) must be set in order to achieve a mean dose at the position of the minimum dose that is three standard deviations (3σ) greater than the prescribed absolute minimum dose; at the same time, the irradiation parameter must allow for a mean dose at the position of maximum dose 3σ less than the prescribed absolute maximum dose. Even when using such an approach there is still the inevitable risk that a very minute portion of mass will receive a treatment outside

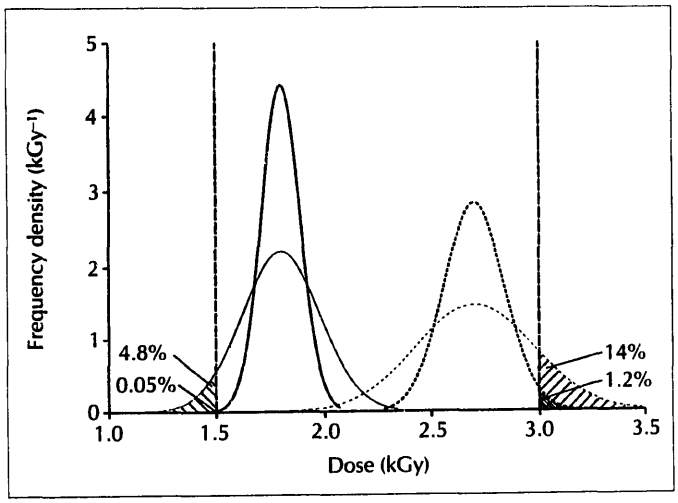

Fig. 2

The concept of limiting minimum and maximum dose values illustrated using the regulation for chicken in the USA as an example. The legal limits are 1.5 kGy and 3.0 kGy. Assumptions: the mean values for minimum and maximum doses are set at 1.8 kGy and 2.7 kGy, respectively; standard deviations are 5% (thick lines) or 10% (thin lines) of the mean. Shaded areas show the probabilities that minimum and maximum measurements will fall below or above the legal limits.

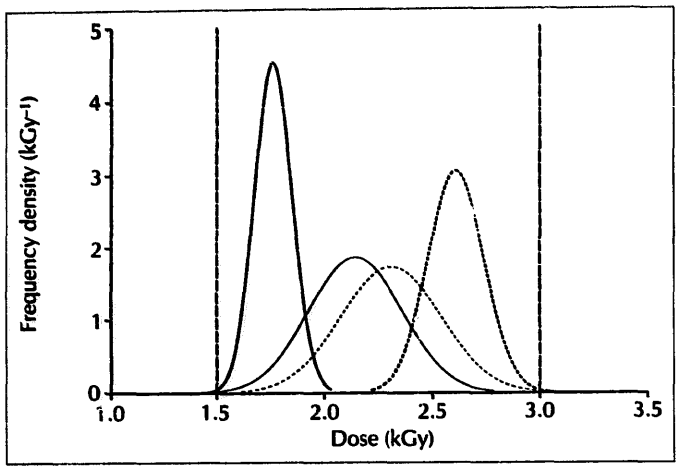

Fig. 3

The consequences of 'absolute' limits for minimum and maximum dose values based on the regulation for chicken in the USA. The legal limits are 1.5 kGy and 3.0 kGy. Assumptions: standard deviations (σ values) are 5% (thick lines) or 10% (thin lines) of the mean; the means are set at 3σ from the limits (that is, 1.76 kGy and 2.61 kGy for σ = 5%, and 2.14 kGy and 2.31 kGy for σ = 10%); and the probability of measurements falling outside the limits is 0.05%.

the legal limits, as is the case with any technical process. On the other hand, the enforcement of such a strict approach ignores the technical constraints of the process: the consequence (shown in Fig. 3) is that the mean dose values measured at the locations of expected minimum and maximum dose approach each other and the uniformity ratio is 1.08 (the range is 2–3 in existing commercial facilities). Furthermore, it must be kept in mind that the assumption that σ is 5% of the mean (see Figs 2 and 3) is based on the inherent accuracy of a routine dosimetry system alone, while the assumption that σ is 10% of the mean is based on the combined effects of dosimetry and processing variations. In practice, it is impossible to conduct radiation processing under such restrictive premises at reasonable costs.

Radiation quantities suitable for official monitoring

The discussion above reveals that some of the legal requirements set out in food irradiation regulations cannot be enforced by authorities. For example, there is no way of measuring the 'overall average dose'; this quantity can only be estimated from information about dose distribution patterns established during dose mapping at irradiation facilities and from records of minimum and maximum doses laid down in the log books of irradiation facilities following process control.

Most regulations do not specify the volume that has to be controlled; however, an average is only well defined when the reference extent is known. The problem with 'overall average dose' is the open definition of its extent – it refers to all the food consumed during a reasonably long period. Such a problem might be eluded as in the regulations of the UK (see Table 1): the reference is defined as the 'batch', which might be very small or extremely large depending on the circumstances. As mentioned above, this use of the 'batch' stands the JECFI findings on their heads, but at least the inspector has a good chance of being able to verify this quantity. The proposed regulations of the EC fall far behind any reasonable concept: specifications concerning the upper limit are missing, and the reference extent for 'overall' is not defined.

The dosimetric quantities that are, by their nature, amenable to control by authorities are found in the record books of irradiation facilities. As discussed above, these records log maximum and minimum dose values together with information about the dose pattern in the product and the technological fluctuations of the process. With a basic knowledge of dosimetry and radiation processing technology the inspector would be able to read and interpret such documentation. This will become even more important under the rules of the EC, as control will become more and more decentralized and the inspector of one member state will not necessarily be allowed to inspect a facility in another member state. In future all such quality enforcement, including monitoring of food production and processing, will be based on evidence of protocols. Any kind of limiting dose values specified in a regulation for food irradiation would thus become amenable to official control by authorities.

As a consequence, it is very important that food control authorities responsible for developing regulations understand the principles of food irradiation technology, and produce definitions that are suitable for practical application and that avoid ambiguities and vagueness. Furthermore, inspectors not only need to understand the philosophy behind a regulation, they also need thorough training in the field of irradiation technology and process control. Finally, inspectors should be able to give advice to processors and both translate and enforce regulations.

Outlook

Prudent and long-sighted authorities have already seen to it that their officials are experts in food irradiation as well as in other food processing technologies. For this reason, some official laboratories are active in the development and inter-laboratory testing of analytical methods for the identification of irradiated foods. However, only a very small number of officials have already acquired deeper insight into the technology, for example by training through the Food Irradiation Process Control School (FIPCOS; see Box 1) of the International Consultative Group on Food Irradiation (ICGFI). FIPCOS aims at the transfer of knowledge as demanded in the Codex Alimentarius Standard[5] for the personnel of food irradiation facilities. At present, it is the only such instruction programme available. The training is available to food inspectors and control officials as well as to operators of irradiation facilities. It is obvious that the competence of control officials and inspectors needs to be on the same level as that of operators; both groups need to be able to communicate with one another appropriately; furthermore, the everlasting competition with criminals (who may misuse any food technology) makes knowledge and competence a prerequisite.

Box 1. The Food Irradiation Process Control School (FIPCOS)

Information available from:

ICGFI Secretariat
Joint FAO/IAEA Division
PO Box 100
A-1400 Vienna
Austria

Courses in 1993[a]:

For operators: Montreal, Canada
7–25 June

For inspectors: Budapest, Hungary
27 September – 8 October

[a] The next courses are scheduled for 1995

The existing regulations on food irradiation have been developed on the basis of experience with other food processes. However, it is obvious that the particularities of this new irradiation technology have not yet been taken into account. Therefore, where possible, existing regulations should be revised and redesigned to meet the needs of both processing and control. The challenge to authorities is now to prepare for the international market in irradiated food. Control and inspection has to take into account the diverging nature of the existing national regulations and the need to estimate regulated quantities. This can only be achieved after control officials and inspectors have acquired a thorough knowledge of the technology of radiation processing, for example through appropriate training courses, so that radiation processing and its control can ultimately contribute to food safety.

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