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DOSIMETRY AND IDENTIFICATION AS A TOOL FOR OFFICIAL CONTROL OF FOOD IRRADIATION

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ABSTRACT

For many years authorities have been concerned about irradiated food being on the market without clearance and appropriate approval. Now, while the practical utilization of radiation processing of food is growing, detection of illegally irradiated food is no longer the main challenge to authorities. The task of official control of food irradiation and the available tools of dosimetry and identification are discussed. Their relevance with regard to the several types of regulations is analysed. Detection of irradiated products which are not labelled is now possible for any likely application of food irradiation. It may also become possible to detect products which falsely claim to have been irradiated. Verification that a product has been irradiated within specified dose limits must rely on dosimetry and the records thereof at the irradiation facility. This is very important for the enforcement of Good Irradiation Practice.

KEYWORDS

Official control; dosimetry; identification; labelling; food irradiation; lawful cases; unlawful cases.

INTRODUCTION

In the early days of radiation processing of food there was no concern at all about labelling. With the emergence of public concern about health risks possibly associated with food, labelling became compulsory with very detailed and specific regulations. The initial intention of labelling regulations was to provide warning information with regard to possible health hazards associated with chemical additives or residues in the food. The right of the consumer for information and free choice is now generally acknowledged and accepted. This has been extended to include other information, especially on the nature of 'organic' food or on the method of production pertaining to religious requirements. Food processed by ionizing radiation is no exception; consumers who for their own reasons wish to avoid such food must be given the choice by appropriate information.

Everyday experience teaches that available techniques may also be misused for some purpose; food irradiation, again, is no exception and fraudulent uses are rare, but do exist. For such reasons, it is essential that authorities have reliable methods for control. Dosimetry at irradiation facilities and the inspection of log-books there, is the main contribution. It is complemented by methods of analytical detection and dose estimation methods applied to samples from the market.

With the emergence of radiation processing as a new technology parliaments and governments became concerned and regulations for its application to food were introduced, as the food legislation until then had not mentioned ionizing radiation. The philosophy differs widely from country to country, but essentially the process was banned, except special permissions granted for individual food items or for goups or classes of food. Under these circumstances, analytical detection methods suitable for enforcing the ban and controlling the few exemptions became of uttermost importance. Consequently, through national programmes and in an internationally concerted action, detection methods were developed, tested and standardized, and these now constitute a reliable tool in the hands of authorities. However, the number of clearances and, hence, the extent of commercial exploitation of food irradiation has meanwhile increased world-wide. Despite that obvious development, authorities in general were not and are not yet prepared to control food irradiation once it is legalized. In this context, it must not be overlooked that in many instances regulations on food irradiation are not developed in a way which facilitates control and inspection.

This contribution will briefly discuss the types of regulations and the methods available for dosimetry, identification and official control. From this, several combinations will be derived for the lawful and unlawful conduct in radiation processing of food and marketing and the consequent tasks and possibilities for control by authorities will be derived.

REGULATIONS

Regulations may be grouped into several classes according to the type and manner in which dose ranges are specified. The clearance methodology, involving individual food items and particular applications or providing for wider groups or classes of food, will not be discussed here.

The Total Ban

Several countries have an explicit ban on any radiation processing of food in their legislations; others which do not mention this technology also imply a complete ban. Usually the utilization of ionizing radiation for inspection purposes (foreign materials, fillings etc.) is termed not to be irradiation. And of course, the doses of up to 1 Gy applied and regulated for such applications do not fulfil any useful food processing purpose. This 'zero' dose of about 1 Gy would be difficult to enforce by analytical detection methods; the 'gray range' up to the lowest dose which fulfils a technically useful purpose (about 20 Gy for sprout inhibition for some potato varieties) is difficult to monitor, but detection methods are also becoming available for some applications at very low doses.

Absolute Limits

Many countries were prudent and long-sighted enough in their regulations to fix only absolute upper dose limits. This approach is justified for health protection considerations and for the purpose of enforcing Good Manufacturing (GMP) and Good Irradiation Practices (GIP) and to preclude that no unnecessarily high treatment be utilized. Absolute limits are easy to enforce as the rules are unambiguous. Any single measurement regardless of dosimetry system falling above that limit is illegal. In certain applications it may also be justified to regulate lower absolute limits in order to eliminate some health hazard (eg Salmonella) or for quarantine purposes (eg elimination of fruit fly). In practice, such legally fixed absolute lower limits easily comply with the technological constraints of the process, ie achieving the minimum effective dose throughout the product. Also combinations of absolute upper and lower limits may be applied in specific cases, regardless of how difficult the setting of process parameters for achieving some tight bounds might be.

Most recently, in a few regulations setting process bounds around the mean value, the upper limit

was related by a factor (1.5, eg UK and Netherlands) to the mean value and the lower limit was related to the upper limit by a factor of 3. Such regulations are completely equivalent to directly setting absolute limits. Either way of specifying absolute limits is likewise effectively enforced by official control of food irradiation.

Unlimited Ranges

The concept of 'overall average dose' as defined by JECFI in 1980 has led many governments to regulate average doses. In doing so it was overlooked that this concept had been specifically introduced for the purpose of toxicological evaluation and that in the Codex Alimentarius General Standard of 1983 limits of 15 kGy were introduced for the average doses of 10 kGy. When regulations used the terminology of 'overall' for average doses it was also overlooked that, in principle, 'all' is not available for inspection and that information on the extent of the lot for which the mean is to be determined, needs to be specified. It is, furthermore, not practical to try to expand this fundamental toxicological consideration and to vary the sole value of 10 kGy to lower dose values of practical applications of processing food by ionizing radiation.

Above all, in many regulations using the terminology of averages, it was also overlooked that a mean always implies that half of the product under consideration receives doses above that value and that the legal acceptability of a treatment above the specified value depends on information about the doses received by other lots of goods which are not under consideration and which might have received the compensating treatment below the average. Usually, authorities would not be concerned about items receiving less then the regulated average but, of course, the same considerations as before apply and an individual item treated below the regulated average is only legally acceptable when the dose to other items on the market is known and compensates for the treatment below the prescribed average.

Any such unlimited ranges or unbound averages regardless of the dose value specified, by their nature, cannot be enforced by official control. This is true especially when the collection of items from which the mean is to be determined remains undefined (eg draft Directive of the European Community).

METHODS OF DOSIMETRY

Dosimetry at food irradiation facilities is always recorded in the log-books together with process control information. Dosimetry and the records thereof are, therefore, the main object of inspection. Such dosimetry at the facility is also repeatable, reproducible, reliable, accurate and traceable to national and international standards. Consequently such dosimetry lends itself to inspection and official control.

Also under investigation are systems which may be read repeatedly and which may be archived for that purpose. Such archived dose meters might allow for reading again during official inspection. Such re-readable dose meter systems could be labels attached to the radiation processed goods changing colour or any other suitable property which can be easily measured by handheld instruments during inspection. Of course, such measurements on label or archived dose meters could only reveal individual situations. Furthermore, the expected locations where the maximum and minimum doses are most likely to occur are often not accessible and the reading on a label dose meter at some other or reference location is not always linked in a reliable manner to the maximum and minimum doses in the goods. Thus, dosimetry cannot contribute too much to the control of the food irradiation process unless records of dosimetry at the irradiation facility and dose mapping data are used as a source of information.

METHODS OF IDENTIFICATION

Within the last 20 years considerable progress in instrumentation and methods for analytical detection of food processed by ionizing radiation has been made. This progress was not conceiveable before. For any application of food irradiation a method for the detection of such treatment is now available (cf. final report of ADMIT, Belfast, 1994, to be published); several methods, at present, are being converted into reliable routine methods and standards for their utilization are being developed by means of international co-operation. Some of the methods even allow for the estimation of the absorbed dose. Depending on the type of the clearances (see above), dose values derived during identification approaches could have clear implications for inspection of the process and for the enforcement of the law.

METHODS OF OFFICIAL CONTROL

Authorities may in principle use both dosimetry and identification for their purposes. Of course, in any case inspectors do not apply the respective experimental techniques themselves, but rely on the services of others. In this context, inspection of the records at the irradiation facility and estimation of the proficiency of the personnel is the main method of control. The data in the log-book collected over prolonged periods also provide insight into the statistical nature and all the fluctuations and variability. This inspection also makes evident the safety margin established through dosimetry and process control between the doses actually achieved and any legal dose limits. By compiling data from several facilities, information on the general situation and on doses received by food on the market can be generated.

Identification methods always render actual data and information on the general situation is not available. As long as regulations specify absolute dose limits, a dose value derived during identification procedures has also clear implications. If the read value - taking into consideration the accuracy of the respective method - is outside the set limit, the treatment is termed illegal. Thus, accuracy and reproducibility of dose estimation in identification procedures may have severe consequences when treatment margins are kept small with the help of very accurate dosimetry systems and very tight process control at the irradiation facility.

APPLICATIONS BY CASES

There are several combinations for grouping the possible situations into categories logically: with respect to stating or not stating that the product is irradiated and with respect to whether factually the product has been irradiated or not. There are altogether four possible alternatives or combina tions; two constitute lawful conduct, two are unlawful. The unlawful combination of situations of

Table 1. Matrix of possible cases

label 'irradiated'	lawful	unlawful
no	not irradiated	irradiated
yes	irradiated within limits	not irradiated or irradiated outside limits

labelling as 'irradiated' where irradiation has not taken place is complemented by having it irradiated outside the legal dose limits. It must not be overlooked that the majority of cases will always fall within the lawful conduct category. In the following, the four possible combinations are presented.

Lawful Cases

Not Irradiated (and Not Labelled). Of course, a product not irradiated must not be labelled as if it were irradiated; the fact that radiation processing has not been applied, under most legislations, must not be mentioned on the label. However, sometimes a claim on origin or on superior quality as a consequence of special treatment is made on the label which is not justified; for such cases tools for the enforcement of the laws are needed by the authorities. Dosimetry and inspection of the records cannot help in the case of unirradiated products as they - obviously - do not exist. It is impractical to consider inspecting all existing facilities and proving a non-treatment. Only new, semi-quantitative identification methods can help to prove that the estimated dose is at least below the detection limit and, therefore, an effective treatment has not been applied.

Irradiated and Labelled (ie within Dose Range). This case seems to be clear as dosimetry and records thereof must be available and the wide range of detection methods including semi-quantitative dose estimations would provide an additional proof. Unfortunately, this is not the complete truth as, on the top of it, dose ranges must be established. As far as dosimetry and the records thereof are accessible maximum and minimum dose values and also means for batches or larger consignments can be calculated. If not accessible (eg for imports), semi-quantitative identification methods give a range of the most probable dose for the single item under investigation, but conclusions about the average are virtually impossible. Of course, long-term monitoring of samples from the market place through appropriate statistical investigation could render estimates on dose distribution characteristics of the irradiated goods on the market. More important, semi-quantitative methods of detection will for some considerable time not reach metrological properties and quality. This implies that - even with the help of such detection methods - stringent and legally binding conclusions on maximum and minimum doses are not possible and are unlikely to stand up in court.

Unlawful Cases

Irradiated but Not Labelled. This is the standard situation for which all the identification methods were originally developed. Dosimetry and inspection of records cannot contribute here, because of the missing label no trace back is possible.

Not Irradiated but Labelled 'Irradiated'. In cases where the irradiation facility is specified on the label (prudent practice of some countries) the irradiation facility could at least be traced with the help of the shipping documents, and the usual inspection procedures would unveil the true situation. Otherwise, the consequences are quite similar to the situation with the non-irradiated and non-labelled product: only the most modern semi-quantitative methods could reveal that the actual dose was below the detection limit and consequently no effective radiation treatment has been applied.

Irradiated and Labelled but Treated Outside Dose Limits. As discussed above for a treatment within the legal limits, dosimetry and the records thereof are the only reliable means to answer questions on dosimetry and on probabilities for partial treatment of some goods outside the given limits. The metrological properties of dose estimations by detection methods would, at least in the near, future not be high enough to allow for conclusive judgements on dose ranges.

CONCLUSIONS

Official control of food irradiation must rely on two complementary tools, namely dosimetry and identification. Semi-quantitative analytical detection methods are of additional value for inspection and for enforcement of the law. However, it is impossible to rule out doubts in situations where a products has not been irradiated and, consequently, is not labelled for such treatment. With the help of some semi-quantitative detection methods it might become possible to identify products which claim to be irradiated but factually are not. For products legally irradiated and labelled as such, only dosimetry and the records thereof can render reliable information on dose ranges applied and maximum or minimum dose limits respected and, thus, contribute to the enforcement of Good Irradiation Practice.