

AUDIT
REPORT

Targeted Audit to Verify
Compliance with Marginal,
Localised and Restricted
Legislation

NOVEMBER 2014



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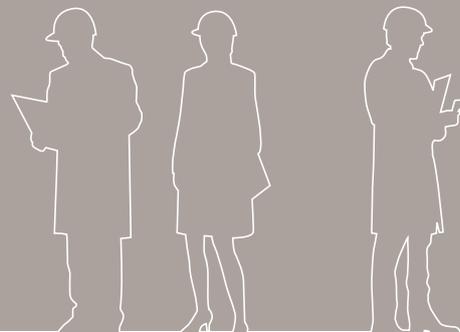


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1. GLOSSARY

FSAI	Food Safety Authority of Ireland
HSE	Health Service Executive
MLR	Marginal, Localised and Restricted
PEHO	Principal Environmental Health Officer

2. EXECUTIVE SUMMARY

The objective of this audit was to assess compliance with the requirements of Health (Definition of Marginal, Localised and Restricted Activity) (Butcher Shop) Regulations, 2010 (S.I. No. 340 of 2010). These Regulations define 'marginal, localised and restricted (MLR) activity' for the purposes of Article 1(5) (b) (ii) of Regulation (EC) No 853/2004.

Audits were carried out in premises supervised by the Environmental Health Service of the Health Service Executive (HSE). Food business operations chosen for audit were selected following a review of self-declarations made by butchers to the HSE in 2011. Eight food business operations were visited. Of these, three were found not to be in compliance with the requirements of Health (Definition of Marginal, Localised and Restricted Activity) (Butcher Shop) Regulations, 2010 assessed by the audit team.

In light of the findings of this audit, the non-compliant food business operators need to implement corrective actions to address the findings identified, and the HSE should:

- Take appropriate follow-up action to ensure/verify that the non-compliant establishments identified achieve full compliance with the Regulations
- Review the wider compliance of butcher shops with the Regulations

3. INTRODUCTION

The Food Safety Authority of Ireland (FSAI) has overall responsibility for the enforcement of food law in Ireland, predominantly through service contracts with Government departments and agencies. The FSAI carries out targeted audits of food businesses to determine the level of compliance with food law and the effectiveness of its enforcement.

The objective of this audit was to assess compliance with the requirements of Health (Definition of Marginal, Localised and Restricted Activity) (Butcher Shop) Regulations, 2010 (S.I. No. 340 of 2010). These Regulations define 'marginal, localised and restricted activity' for the purposes of Article 1(5) (b)(ii) of Regulation (EC) No 853/2004. These Regulations define 'marginal, localised and restricted (MLR) activity' as follows:

Marginal	Total supply of food of animal origin to all customers is on average less than 2,000kg per week OR Total supply of food of animal origin to other retail establishments is on average, no more than 25% by weight of total supply of food of animal origin.
Localised	Supply of food of animal origin to other retail establishments is within 100km of your establishment.
Restricted	<ul style="list-style-type: none"> • No supply to other retail establishments of ready-to-eat food of animal origin prepared or processed in your establishment. • No supply to other retail establishments of on average, more than 250kg per week on an annual basis in total of minced meat, meat preparations made from minced meat or meat products made from minced meat prepared or processed in your establishment.

All butcher shops have to meet the general hygiene requirements set out in Regulation (EC) No 852/2004 on the hygiene of foodstuffs and must be registered as a food business with the HSE. Butcher shops supplying other retail businesses, i.e. other shops, butcher shops (including other branches of the same business), catering, canteens, restaurants, hotels, pubs, etc. and meeting the MLR activity criteria set out in S.I. No. 340 of 2010 will remain subject only to the requirements of Regulation (EC) No 852/2004.

If however, retail butcher shops are wholesaling quantities of meat which exceed the MLR criteria, they must, in addition to meeting the requirements of Regulation (EC) No 852/2004, also comply with Regulation (EC) No 853/2004 which lays down specific rules for food of animal origin. In these instances, instead of being registered and supervised by the HSE, such food business operations will require approval under Regulation (EC) No 853/2004 and will be supervised by the local authority. Transfer of supervision from the HSE to the local authority will be carried out according to an established protocol.

To determine the extent of wholesale trade being conducted by butchers, the HSE in 2011, circulated a questionnaire asking them to assess their activities against the MLR criteria. Butchers were asked to complete the questionnaire and sign a declaration that the information supplied in the form was correct and on the understanding that it would be subject to the verification by inspectors from the HSE or the local authority. This self-declaration document was one of the criteria used by the FSAI audit team.

Butchers, when signing the form, also declared that they understood that it was an offence under Regulations 4 and 6 of S.I. No. 340 of 2010 to make a false or misleading statement in this regard and would have to:

- Produce on request, records which prove compliance with MLR criteria to the satisfaction of inspectors
- Keep these records for two years
- Notify the inspectors of any change in meat sales which would affect the decision of the inspectors

3.1. Audit Objective

The objective of this audit was to assess compliance with the requirements of Health (Definition of Marginal, Localised and Restricted Activity) (Butcher Shop) Regulations, 2010 (S.I. No. 340 of 2010).

This targeted audit of compliance by butchers with MLR legislation was carried out as part of the planned programme of audits undertaken by the FSAI in 2014.

3.2. Audit Scope

During the audit, the FSAI audit team assessed food business operator compliance with the audit criteria set out in Health (Definition of Marginal, Localised and Restricted Activity) (Butcher Shop) Regulations, 2010 and the self-declaration completed in 2011.

3.3. Audit Criteria and Reference Documents

The principal audit criteria referred to during the audit were:

- Health (Definition of Marginal, Localised and Restricted Activity) (Butcher Shop) Regulations, 2010 (S.I. No. 340 of 2010)
- The self-declaration form completed by food business operators
- [FSAI and HSE Service Contract](#) (including [Food Safety Authority of Ireland Act, 1998](#) (S.I. No. 29 of 1998), as amended)
- [Regulation \(EC\) No 178/2002](#) laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended
- [Regulation \(EC\) No 882/2004](#) on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules, as amended
- [Regulation \(EC\) No 852/2004](#) on the hygiene of foodstuffs, as amended
- Guidance Notes/Codes of Practice and other relevant legislation detailed in the FSAI Service Contract with the HSE

3.4. Audit Methodology

Audits were carried out in premises supervised by the Environmental Health Service of the HSE. Food business operations chosen for audit were selected following a review of self-declarations made by butchers to the HSE in 2011. Two butcher shop premises were assessed in each of four Principal Environmental Health Officer (PEHO) local health areas.

The audit comprised of an on-site visit where compliance with MLR criteria was assessed by:

- Establishing the list of customers who were not over the counter sales
- Establishing the list of suppliers of food of animal origin
- Inspection of related records including: delivery dockets, invoices, etc.
- Physical checks
- Review of financial records

Because the audit was conducted on a sample timeframe of the food business operator's activities, the findings reported reflect compliance or non-compliance during this period.

A report on the audit findings in each butcher shop visited was sent to the food business operator and was copied to the PEHO for follow-up where necessary.

4. AUDIT FINDINGS

A total of eight butcher shops were audited. The number of other retail establishments to which meat and meat products were being wholesaled ranged from three to 30. Findings regarding the specific requirements relating to MLR are detailed below.

4.1 Regulation 3(1)

An activity may be regarded as "marginal" only if either –

- (a) The food business operator's total supply of food animal origin (to all customers including retail establishments) is on average less than 2000kg per week, or***
- (b) The food business operator's supply food of animal origin to other retail establishments represents, on average, no more than 25%, by weight, of the total supply of food of animal origin***

Finding

One food business operator's total supply of food of animal origin was determined to be, on average, in excess of 2,000kg per week and it was established that the supply to other retail establishments was on average, more than 25%, by weight of this total.

All other establishments were found to be compliant with this regulation.

4.2 Regulation 3(2)

An activity may be regarded as “localised” if the food business operator supplies food of animal origin to other retail establishments only within 100km of the supplying establishment.

Finding

All establishments assessed were found to be compliant with this regulation.

4.3 Regulation 3(3)

An activity may be regarded as “restricted” only if the food business operator does not supply other retail establishments with either –

- (a) Ready-to-eat food of animal origin, or*
- (b) On average, more than 250kg per week in total of minced meat, meat preparations made from minced meat or meat products made from minced meat, prepared or processed in his or her establishment.*

Finding

One food business operator was found not to be compliant with Regulation 3(3)(a), whilst another was found not to be compliant with Regulation 3(3)(b).

All other food business operators were found to be compliant with this Regulation.

4.4 Regulation 4(3)

Regulation 4(3) states that to prove an activity is ‘marginal, localised and restricted’ as defined in Regulation 3, the food business operator shall produce, at the request of an authorised officer, all documents or records which prove that the activity satisfies the requirements of Regulation 3.

Finding

All food business operators demonstrated compliance with regulation 4(3) by providing relevant information and documentation, which included order books, invoices and delivery dockets relating to trade with other retail establishments.

5. POSITIVES PRACTICES OBSERVED DURING THE AUDIT

Food business operators audited were in all instances in a position to produce the required documentation and records to allow the FSAI audit team assess their wholesaling activities to determine compliance with MLR criteria.

6. CONCLUSION

Of the eight butcher shop establishments assessed by the audit team, three were found not to be in compliance with those requirements of Health (Definition of Marginal, Localised and Restricted Activity) (Butcher Shop) Regulations, 2010 assessed by the audit team.

7. RECOMMENDATIONS

In light of the findings of this audit, the HSE should:

- Take appropriate follow-up action to verify that the non-compliant establishments identified achieve full compliance with the Regulations
- Review the wider compliance of butcher shops with the Regulations



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