

**LA name & OCD Number**

**Food Standards Scotland**

**Local Authority Food Law Enforcement Services**

**Capacity and Capability Audit**

**Regulation (EU) 2017/625 Checklist – Articles 148 & 10**

**(with reference to Regulation (EC) 853/2004 Article 4)**

| **Regulation (EU) 2017/625 Article 148 Relation with Regulations (EC) No 852/2004 and (EC) No 853/2004 regarding approval of food business establishments** **Regulation (EC) 853/2004 Article 4 Registration and approval of establishments**  |
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| **Regulation (EU) 2017/625** 1. Competent authorities shall establish procedures for food business operators to follow when applying for the approval of their establishments in accordance with Regulations (EC) No 852/2004 and (EC) No 853/2004.2. Upon receipt of an application for approval from a food business operator, the competent authority shall make an on-site visit.3. The competent authority shall approve an establishment for the activities concerned only if the food business operator has demonstrated that it complies with the relevant requirements of food law.4. The competent authority may grant conditional approval if it appears that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new official control of the establishment, carried out within three months of granting conditional approval, that the establishment meets the other relevant requirements of food law. If clear progress has been made but the establishment still does not meet all of the relevant requirements, the competent authority may prolong the conditional approval. However, conditional approval shall not exceed a total of six months, except in the case of factory and freezer vessels flying the flag of Member States, for which such conditional approval shall not exceed a total of 12 months. 5. The competent authority shall keep the approval of establishments under review when carrying out official controls.**Regulation (EC) 853/2004**1. Food business operators shall place products of animal origin manufactured in the Community on the market only if they have been prepared and handled exclusively in establishments: (a) that meet the relevant requirements of Regulation (EC) No 852/2004, those of Annexes II and III of this Regulation and other relevant requirements of food law; and (b) that the competent authority has registered or, where required in accordance with paragraph 2, approved. 2. Without prejudice to Article 6(3) of Regulation (EC) No 852/2004, establishments handling those products of animal origin for which Annex III to this Regulation lays down requirements shall not operate unless the competent authority has approved them in accordance with paragraph 3 of this Article, with the exception of establishments carrying out only: (a) primary production; (b) transport operations; (c) the storage of products not requiring temperature-controlled storage conditions; or (d) retail operations other than those to which this Regulation applies pursuant to Article 1(5)(b). 3. An establishment subject to approval in accordance with paragraph 2 shall not operate unless the competent authority has, in accordance with Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption ( 1 ): (a) granted the establishment approval to operate following an on-site visit; or (b) provided the establishment with conditional approval.4. Food business operators shall cooperate with the competent authorities in accordance with Regulation (EC) No 854/2004. In particular, food business operators shall ensure that an establishment ceases to operate if the competent authority withdraws its approval or, in the case of conditional approval, fails to prolong it or to grant full approval. 5. This Article shall not prevent an establishment from placing food on the market between the date of application of this Regulation and the first subsequent inspection by the competent authority, if the establishment: (a) is subject to approval in accordance with paragraph 2 and placed products of animal origin on the market in accordance with Community legislation immediately prior to the application of this Regulation; or (b) is of a type in respect of which there was no requirement for approval before the application of this Regulation |

| **Regulation (EU) 2017/625 Article 148 Relation with Regulations (EC) No 852/2004 and (EC) No 853/2004 regarding approval of food business establishments Regulation (EC) 853/2004 Article 4 Registration and approval of establishments**  |
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| **Question** | **Answer** | **Comments/Evidence** | **Auditors Notes** |
| Does the LA have a documented procedure to ensure that its database is complete for all relevant food and feed premises in its area?What arrangements are carried out in practice?Are these arrangements in line with the LA’s procedures? | Yes/NoYes/No |   | *Procedure/arrangements might include:** *Purchase/use of local business directory info;*
* *The Business rating system;*
* *Formalised mechanisms to update records following inspection/planning or building control applications;*
* *Programmed street surveys;*
* *Comparison with other agency’s/authorities databases;*
* *Promotion of food registration.*

*Auditors note that the Business rating system can be accessed at* https://www.saa.gov.uk/*The resources put in to this by the Authority will depend on factors such a s the rate of turnover of the business, the risk associated with a particular business and adherence to an inspection programme that includes all businesses.*  |
| Is the database accurate? | Yes/No |  | *Auditors may discover inspections, samples or complaints on hard files that have not been recorded on the computer. When searching for computer records duplicate entries may be found.* Checklist and other evidence relating to information held on D/B e.g. duplicate hardcopy records examined during audit and answers to other parts of the audit protocol. |
| How does the Authority control the information entered onto the database? |  |  | *Arrangements might include:** *Restricted access for entering and deleting premise;*
* *Documented input protocols;*
* *Training of input staff;*
* *Mandatory fields;*
* *Dedicated input staff.*
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| How does the LA verify the information held on its database? |  |  | *The effort the Authority needs to expend in checking the database will depend on the amount of users and the number of entries made. Arrangement might include:** *Data management checks e.g. Reports showing missing fields such as risk score, premises usage code etc. Reports showing names and addresses against a particular usage code to verify that they have been correctly allocated.*
* *File audits to check for errors inputting from standard input sheets and whether hard copy files correspond to the information held on computer e.g. copies of inspection forms will indicate where an inspection should be recorded on the computer.*
* *Utilising audit logs to ensure timely updates of records.*
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| Who has management responsibility for the database? |  |  |  |
| Do they take responsibility for recording: * Details of any problem with the system and the action taken?
* User access definitions?
* Configurations of any standard reports?
 | Yes/NoYes/NoYes/No |  | *Some proprietary systems will have reports set up by the computer company. Others have report writing capabilities that are easily understood. Auditors should verify that the person responsible has knowledge of what any standard reports are showing him especially where these are used to monitor compliance with the service plan or make returns to FSS.* |
| Is there a suitable New premises inspections procedures? | Yes/No |  | *All registration forms reviewed and appropriate visits made to new premises? (IC - 3.7.2.2)* |
| Is there a suitable Approvals procedure(s)? | Yes/No |  | *The procedures should cover all categories of Approval relevant to the premises in the LA’s area. Where no premises have been identified that require Approval, the procedures should contain sufficient information to assist officers to recognise such operations and appropriate references to the relevant legislation, guidance and inspection forms.**The procedures should cover the inspection of Approved Premises and the Approval process.* |
| Are registration records accessible to the public? | Yes/No |  |  |