

Local Authority Frequently Asked Questions (FAQ) on the Approval of Establishments

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1. APPROVALS

1.1 MAINTAINING THE APPROVAL CHAIN

Q1.1.1 does the legislation require that approved establishments maintain an “approvals chain” such that approved establishments can only source incoming products of animal origin (POAO) from other approved establishments?

A. There is no *specific* requirement in Regulation (EC) No 853/2004 for approved establishments to obtain POAO from other approved establishments; however, the Regulation *does* generally have this effect (but see the next Q&A for an exception). This is because establishments invariably require approval to be able to supply approved establishments:

- In order for a non-retail establishment to supply POAO to any establishment it will require approval because none of the retail exemptions are applicable.
- In order for a retail establishment to operate with a view to supply POAO to approved (i.e. non-retail) establishments even on a limited basis, it will require approval because it fails to satisfy the ‘retail to retail’ element of the relevant exemption.

For fresh meat, the requirement for it to come from an approved establishment is clearer. In Annex III to Regulation 853/2004, Point 2 of Section VI says:

“All meat ... used to produce meat products must meet the requirements for fresh meat.”

The requirements for fresh meat are contained in Annex III so if meat that is used to make meat products is supplied by an establishment to which Annex III does not apply it is difficult to see how point 2 of Section VI can be satisfied. This places the onus on the FBO to ensure that it only receives meat from an approved establishment, so that it meets the requirements described.

Q. 1.1.2 an FBO in my authority stores dried POAO at ambient and then supplies this to approved establishments for further processing. No repacking takes place; the products are distributed with the original id marked packaging from the establishment of manufacture. Does the establishment storing these products require approval to allow legitimate supply to a UK approved establishment?

A – No, provided that there is no other handling, repacking or processing of raw POAO at the establishment. If the FBO is simply engaged in storage and transport of ambient food, then they are exempt from the requirement for approval by virtue of Article 4(2) (b) and (c) of Regulation (EC) No. 853/2004.

There is no specific requirement for approved premises to source their incoming materials from approved establishments. While in most other scenarios Regulation (EC) No 853/2004 does have that effect (see answer 1.1.1); in this specific example approval is not required and the products can be distributed to approved establishments.

Q1.1.3 An FBO in my authority producing composite products is not subject to approval under 853/2004. Another FBO that they are supplying to in another member state is questioning why the products do not bear an ID mark and whether the FBO is approved – can I approve the establishment so that they are able to continue to supply to their customers?

A. No – Applications for approval of establishments should only be accepted from food business operators that intend to engage in activities for which approval would be required in accordance with Regulation 853/2004. Under no circumstances should approval be granted to an establishment which is not subject to approval under Regulation 853/2004. For example, the FBO in question is only assembling composite products from processed POAO and products of plant origin, this is not subject to 853/2004 and approval can't be granted for assembly of composite products. If the FBO in the other member state refuses food products from the supplying UK FBO on the basis that it is not ID marked when it is not required under EU legislation then this is a commercial issue between the two FBOs.

However, if the FBO was previously exempt but now wishes to supply POAO to approved establishments, they may now be subject to approval, for example if they:

- No longer supply only to the final consumer and to retail/catering on a localised, marginal and restricted basis,
- Handle, process and sell POAO as well as assembly of composite products

If the scope of their activities changes such that they become subject to approval, the FBO has a duty under the EU hygiene regulations* to notify you and apply to your Authority in the normal way to seek approval.

*Article 6, 2 of Regulation 852/2004

1.2 COMPOSITE PRODUCTS

Q1.2.1 (a) An establishment wishes to manufacture a frozen yoghurt product. They purchase processed, pasteurised yogurt, add fruit/fruit flavours and freeze this product. Does this require approval?

A. Where an FBO purchases yoghurt from an approved establishment and then combines it with other foods/flavourings of plant origin, and processes them together to make the final product, only Regulation 852/2004 would apply and approval would not be required. However, if raw milk/and or processing (i.e. heat treatment) is involved in making the yoghurt, then approval would be required under Regulation 853/2004 for this activity.

(b) Does the same apply to manufacture of ice cream?

A. With regard to ice cream it could be classed as a “composite product” where it merely involves combining food of plant origin with processed POAO e.g. pasteurised milk or cream, and either placed on the market as such, or further processed together.

Guidance from the EU Commission gives the manufacture of ice cream using pasteurised incoming ingredients added to products of plant origin as a specific example of a process not requiring approval¹.

In both scenarios, if the processed POAO is re-processed before the addition of any products of plant origin then that activity is subject to approval and the establishment would therefore need to be approved.

Q1.2.2 An establishment in my area which manufactures scotch eggs now wishes to make vegetarian scotch eggs as well. They have no retail element and do not supply to the final consumer. Do they need approval for this new activity? If so do they need to apply formally for approval for this additional activity?

¹ http://ec.europa.eu/food/food/biosafety/hygienelegislation/docs/guidance_doc_853-2004_en.pdf

A. This will depend on how the FBO proposes to produce the vegetarian scotch eggs. If they process raw shell eggs to produce the filling and then combine it with it products of plant origin, then this will be an additional approvable activity as there is processing of raw POAO (eggs). If however, the FBO simply combines egg processed in another approved establishment with the vegetarian ingredients then this would be a composite product and would be exempt from approval.

In either scenario, an FBO needs to advise their LA of the change; Article 6(2) of Regulation 852/2004 requires FBOs to notify the competent authority of any significant changes in activities. Material changes to the HACCP-based procedures in place in an establishment should be considered as a significant change in activities.

If the activity is subject to approval, then the FBO needs to apply to you for approval before commencing the activity and an assessment needs to be made in the same way as for a new approval.

Please refer to the FSA approvals guidance for more information.

Q.1.2.4 An approved establishment in my area produces ready meals which are sold to other establishments. It has been noticed that all of the ready meals bear an ID mark. The meals in question are pasta based and have processed POAO added to them, for example cheese and ham. Does manufacture of these products require approval and should they bear an ID mark?

A. If the cheese and/or ham are being supplied to the FBO already processed from other approved establishments and then being assembled with products of plant origin (pasta and vegetables in this case), these would appear to be composite products and exempt from approval under Regulation 853/2004. If the FBO uses raw POAO and processes them on site and then adds to the meals, the activity of processing the POAO would require approval and the establishment must be approved.

Within the EU Commission Guidance for 853/2004² – Annex II there is a non-exhaustive list of processed products of animal origin:

² http://ec.europa.eu/food/food/biosafety/hygienelegislation/docs/guidance_doc_853-2004_en.pdf

“Processed products are obtained by submitting raw products to a process such as heating, smoking, curing, maturing, drying, marinating, etc. The process must lead to a substantial alteration of the initial product.

- *Meat products (ham, salami, etc.)*
- *Processed fishery products (smoked fish, marinated fish etc.)*
- *Dairy products (heat treated milk, cheese, yoghurt, etc.)”*

The guidance also states that

Meat and/or dairy products used to prepare ready-to-eat meals composed of such processed products and vegetables must have been obtained in accordance with Regulation (EC) No 853/2004, but the manufacture of these ready-to-eat meals falls under Regulation (EC) No 852/2004

However, if the FBO is approved for other activities then it can apply its ID mark to composite products if it chooses as well as those subject to approval:

“If an establishment manufactures both food to which this Regulation applies and food to which it does not, the food business operator may apply the same identification mark to both types of food³.”

1.3 COLD STORES

Q. 1.3.1 I have a cold store in my area which stores and sells POAO to retailers and caterers only. Does this require approval?

A. Yes if the cold store stores POAO supplied from other establishments and sells them to caterers and retailers, then this is subject to approval.

However, cold stores that are only part of an integrated logistical chain for distribution to specific retailers, POAO which are packaged for retail sale to the final consumer and where activities are physically limited to transport or storage are exempt from approval.

This does not apply to cold stores which store POAO which is packaged for retail sale and sell this to other establishments because the activity of selling POAO to other establishments (approved establishments, retail establishments, catering establishments) means that the FBO's activities are not limited to storage and

³ Annex II, section I, part B (7) of Regulation 853/2004

transport. Activities limited to storage or transport refer to cold storage by an FBO of their own products.

Generally, cold stores will require approval, unless they operate in a way that is exempt from Regulation 853/2004, for example if they have a genuine retail element and/or only store and distribute composite products (e.g. pizzas, ice cream etc.). More details can be found in the letter to all LAs (ENF/E/15/002⁴) and will be included in the FSA guidance on the Approval of Establishments.

Note: Where a cold store is exempt (e.g. because it has a retail element and supplies only to other retailers and on a local, marginal and restricted basis) then the specific temperature requirements for POAO in Regulation 853/2004 will still apply.

1.4 APPROVAL NUMBERS AND CHANGE OF OWNERSHIP

Q1.4.1 An approved establishment is moving to new premises. Can the FBO retain their existing approval number?

A. This might be possible, providing that all of the following criteria are met:

- The move is to a premises within the same Local Authority area
- The ownership of the FBO (and “controlling mind” of the business) remains the same
- Traceability is not compromised in any way

Where these criteria are met, and following discussion and agreement from the Competent Authority, retaining an approval number may be possible. Where this is the case, the approval will need to be surrendered by the FBO and then the same number re-issued at the new establishment, once that establishment has been approved by the LA. This is to ensure that the approval number remains unique and that there is no overlap in operations which would mean two sites using the same number concurrently. The process should be fully documented in the approval documentation

Q.1.4.2 An approved establishment in a neighbouring authority will be relocating to new premises in my authority. Can the FBO use up their existing packaging, pre-printed with their existing approval number from the neighbouring authority,

⁴ <http://www.food.gov.uk/sites/default/files/ENF-E-15-002.pdf>

for a short time? Once used up they intend to switch to new packaging with the number which my authority issues to them.

A. No – this is not permissible. The Agency’s view is that the practice of allowing POAO to bear an identification mark with an approval number other than that of the establishment of production or of processing is contrary to *Regulation 853/2004, Annex II, section I, paragraphs 1 and 7*: “*The identification mark must be applied before the product leaves the establishment*”; and “*The mark must indicate the approval number of the establishment*”.

The only flexibility that could be applied to this requirement would be in the event of a *force majeure* (an extraordinary event beyond the control of the parties involved, for which no reasonable contingency arrangements could be made, such as flooding or fire). Please see the FSA Approvals Guidance for more details about the process which should be followed in the case that *force majeure* might apply – these should be submitted to the FSA for consideration on a case-by-case basis. Contact details for each of the UK countries are included in the Guidance [DN reference or link to be included].

Q1.4.3 A new FBO has taken over at an approved establishment and wants to re-name it. I have confirmed that we as the CA need to reissue the approval. Does the new business need to reapply and can the new business still use the existing approval number?

A. A new approval is needed where there is a new Food Business Operator (i.e. change of controlling mind) at an establishment, regardless of whether the nature of the business remains unchanged. The new FBO will need to apply for new approval before they carry out any activities subject to approval. If approval is granted (i.e. if it meets the requirements in the food hygiene regulations), ideally a new approval number should be issued for the establishment; however regard can be given to allowing a business to retain the number if the business is to continue to operate from the same premises and in essentially the same way, i.e. the type of food production by the business and the food safety control arrangements of the business will remain essentially the same. See approvals guidance for additional detail.

Where there is a change of name **only**, but the ownership or “controlling mind” and the nature of the business remain the same, re-approval will not be required. However where there is a change of name, the approval document needs to reflect this and the Agency should be informed. Details of new approvals and updates to existing approvals should be sent to the following email address:

approvals@foodstandards.gsi.gov.uk

executive.support@foodstandards.gsi.gov.uk for approvals in Northern Ireland

Annex 3 of the FSA approvals guidance has more detail on changes in FBO.

1.5 SINGLE ESTABLISHMENT (SATELLITE) EXEMPTION

Q1.5.1 Is advice on the single/satellite establishment principle now available?

- A. This has now been incorporated into the FSA Food Law Code of Practice – The latest version of which was published and came into force on the 7th April 2015⁵. The Code of Practice now includes the criteria that need to be considered when assessing if more than once closely associated premises can be considered to be a single establishment. Please refer to section 3.2.5 of the Code of Practice⁶

1.6 RETAIL EXEMPTIONS AND MARGINAL, LOCALISED AND RESTRICTED CRITERIA

Q.1.6.1 A small bakery in my authority produces a range of products including sausage rolls, pies and other products using raw meat, as a small part of their business. The products are all supplied to local retailers and caterers. The bakery does not sell directly to the final consumer. Does this need approval or do any exemptions apply because marginal, localised and restricted criteria are met as the majority of the production is bread cakes and so on and POAO is less than 25% of the business?

- A. The bakery is subject to approval. The bakery is not a retail establishment and the marginal, localised and restricted (MLR) criteria form part of the retail exemption. The criteria only apply to retail establishments which also sell

⁵ <http://www.food.gov.uk/enforcement/enforcework/food-law-code-of-practice-2015>

⁶ <http://www.food.gov.uk/enforcement/enforcework/food-law-code-of-practice-2015/3-2-registration-of-food-business-establishments#toc-5>

POAO to other retailers – provided the sale of POAO to other retailers is on a MLR basis.

To meet the exemption the component of the retail business which involves sales to other retailers must be:

- **Marginal** – the POAO supplied to other retailers account for up to 25% of the FBO's total turnover in terms of food (or up to 2 tonnes per week sold to other retailers if it is meat only) and;
- **Localised** – sales to retailers and caterers locally (see QXX and the FSA approvals guidance for more details) and;
- **Restricted** – to certain types of products and/or certain types of premises supplied (see FSA approvals guidance for more details of restricted)

Q.1.6.3 (i) We have a catering butcher in our authority who supplies the final consumer but also cuts and wholesales some meat to other retailers and caterers in the authority. This element of the business is approximately one tonne a week. Does this need approval from the FSA?

- A. This catering butcher is likely to be exempt from approval under the MLR exemption available in Regulation 853/2004. Where there is a genuine retail element and remaining supply is to other retailers and caterers only, and that supply is marginal local and restricted then this is exempt by virtue of the retail exemption in Article 1(5)(b)(i) and (ii) of Regulation 853/2004. The FSA's advice is that local should be taken to mean sales within the establishment's own county plus the greater of either the neighbouring county or counties or 30 miles/50km from the boundary supplying establishment's county. For meat, FSA advice is that marginal and restricted is considered to be up to 2 tonnes a week.

Q.1.6.3 (ii) the butcher also buys in primal cuts e.g. Strip loins and cuts/portions these and rewraps. Does he need approval for the activity of rewrapping?

- A. No – the retail exemption means that the butcher is exempt from approval generally as long as the volume of meat which is cut and/or processed and then wholesaled to other retailers and caterers remains less than two tonnes per week. The FBO is exempt on the basis that he is a retailer who has a small element (Local marginal restricted) of sales to other retailers, and retail is exempt from the requirements for approval.

1.7 CUTTING AND FSA APPROVALS

Q1.7.1 at what point does a butcher become a cutting plant?

A. Regulation 853/2004 requires establishments that cut meat and supply this to other establishments to be approved as cutting plants and subject to veterinary control.

Annex III, Section 1, Chapter V of the above Regulation gives information on hygiene during cutting and boning, which states that:

“Food business operators must ensure that cutting and boning of meat of domestic ungulates takes place in accordance with the following requirements.

1. Carcases of domestic ungulates may be cut into half-carcases or quarters, and half carcases into no more than three wholesale cuts, in slaughterhouses. Further cutting and boning must be carried out in a cutting plant.”

A meat cutting plant is defined in the Meat Industry Guide⁷.

Where an Establishment requires FSA approval as a cutting plant further advice can be sought from the FSA Operations approvals team:

Approvals@foodstandards.gsi.gov.uk

Executive.support@foodstandards.gsi.gov.uk (for NI)

If supply is to the final consumer (retail) and to other retailers and on a marginal, localised and restricted basis approval is not required. Details of the Local, Marginal and Restricted Criteria can be found above and in the section on exemptions in the FSA Approvals Guidance.

⁷ <http://www.food.gov.uk/business-industry/meat/guidehygienemeat>

Q.1.7.2 I have an approved meat products establishment in my authority who wishes to cut and/or bone meat at the establishment to use the meat as an ingredient in their own meat products. Do they need approval by the FSA as a cutting plant?

- A. No – approval from the FSA is only needed where the FBO is cutting and/or boning the meat and then supplying this to other establishments. Where the cutting activity is to produce ingredients for their own meat products, the approval remains for production of meat products under the LA jurisdiction.

If the FBO also wishes to supply cut and/or boned meat to other establishments, approval from the FSA as a cutting plant would then be required.

Q.1.7.3 who has enforcement responsibility for POAO which are in transit from an FSA approved establishment (e.g. a slaughterhouse) to another establishment?

- A. Enforcement, if it is needed for any reason, will fall to the LA district the vehicle transporting the goods is passing through. FSA only have enforcement powers and responsibilities within the defined boundaries of FSA approved establishments. However, where the LA needs support or advice from FSA Field Veterinary staff they should contact the FSA on:

approvals@foodstandards.gsi.gov.uk

Executive.support@foodstandards.gsi.gov.uk (For NI)

1.8 EGG APPROVALS

Q1.8.1 should an egg packing centre be approved if it packs small quantities of eggs and supplies to local caterers and retailers?

- A. The small quantity production of eggs exemption is for primary production only (i.e. restricted to production and collection of eggs). Small quantities of eggs can be sold directly to the final consumer without the need for approval. However requirements in egg marketing legislation mean that eggs supplied to caterers and retailers must be Class A. In order to supply class A eggs, the establishment must weight, grade and pack their eggs and that activity of grading & packing goes beyond primary production level which means that establishment needs to be registered with APHA

(Animal & Plant Health Agency, part of Defra) Egg Marketing Inspectors and approved by you as the LA. (Note: in Northern Ireland, egg packing centres will be registered by DARD and approved by the FSA in NI).

As the activity of weighing and grading at egg packing centres, approval would be required.

Further guidance on egg marketing legislation and registration of egg packing centres with the Egg Marketing Inspectorate, can be found on Defra's website:

<https://www.gov.uk/eggs-trade-regulations>

or DARD in the case of food business establishments in Northern Ireland
<http://www.dardni.gov.uk/index/food.htm>

1.9 FISHERY PRODUCTS

Q1.9.1 I have been contacted by a registered fishery products business in my authority asking whether they now require approval for supplying prawns and shrimp to an approved establishment. Prawns/shrimp are caught by fishermen who then blanch them to remove the shell and to have some preservation of the product before supply to an approved establishment to be further processed. Does the process of blanching/boiling the shrimp require approval?

- A. Fishing, the handling of fishery products (without changing their nature substantially) and their transport to the first establishment on land would remain primary products, and, therefore such activities would only require registration. This includes fishery products even after slaughter, bleeding, decapitation, gutting, removing fins, refrigeration and placing in containers for transport. However the products resulting from further handling of fishery products (e.g. filleting, boiling, packaging under vacuum etc.) are not primary products.

From this we can establish that in this case the boiling of shrimps goes beyond the definition of primary products. Therefore, the next question to consider is whether the existing registration is sufficient or the activity requires approval. Establishments that do not fall under the 'retail' exemption would require approval. Such establishments would be subject to the relevant requirements of both Regulations 852/2004 and 853/2004.

So, in this case if an FBO (the fisherman) boils the shrimps for supply directly to an approved establishment for further processing, it would seem that activity would need to be approved.

1.10 MISCELLANEOUS

Q1.10.1 Is the process step of slicing POAO (e.g. cheese) one that specifically requires approval under Regulation 853/2004?

- A. Generally speaking, no, because cheese is already a processed POAO and slicing the cheese is not further processing the cheese. Regulation 852/2004 defines processing as “any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those products” This would mean that activities such as slicing, grating, chilling etc. would fall outside the definition of “processing”. However, if the cheese is supplied to other establishments, approval for re-wrapping is likely to be required. Where POAO, including cheeses, are removed from the original wrapping/package and rewrapped/repacked you need to consider whether approval and application of a new ID mark would be applicable based on other provisions of the Regulations, such as for re-wrapping:

Annex II Section I, A of Regulation 853/2004 states:

- 1. The identification mark must be applied before the product leaves the establishment of production.*
- 2. However, when a **product's packaging and/or wrapping is removed** or it is further processed in another establishment, a new mark must be applied to the product. In such cases, the new mark must indicate the approval number of the establishment where these operations take place.*

Q1.10.2 An establishment in my area carries out re-wrapping activities. They are re-wrapping cooked meat samosas & vegetable samosas, vegetarian samosas and cooked pies containing meat and vegetables. The products come from an approved establishment and have the ID mark on the packaging of the establishment which produced them. Does the FBO require approval as a re-wrapping centre?

- A. The activity of processing the samosas initially would require approval where raw meat and vegetables are combined and then processed (cooked) and so application of an ID mark is appropriate.

If the products in question are then supplied to another establishment, at this stage the cooked samosas contain **processed** POAO combined with products of plant origin and are likely to be composite products which are outside of (exempt from) the scope of Regulation 853/2004. Therefore, although the activity of re-wrapping **POAO** would require approval, composite products are exempt by virtue of Article 1 (2) of Regulation 853/2004 and as such do not have any specific provisions set out in Annex III of the Regulation and re-wrapping them would not require approval.

Although the products will no longer have an ID mark if rewrapped in an establishment which does not require approval, the traceability requirements in Regulation 178/2002 mean that the product will still be traceable back to the re-wrapping establishment and from there to the manufacturer.

Note: If the FBO in question is also re-wrapping POAO, then this is subject to approval and the establishment must be approved. In that scenario, the FBO can apply its ID mark to composite products if it chooses as well as those subject to approval (see above question 1.2.4)

2. ENFORCEMENT AND SANCTIONS IN APPROVED ESTABLISHMENTS

Q2.1 Can I serve a RAN on an establishment in England which requires approval, but is not yet approved?

- A. Yes – Within the Food Safety and Hygiene (England) Regulations 2013 it states that “Where it appears to an authorised officer of an enforcement authority that in respect of **an establishment** that Article 4(2) of Regulation 853/2004 **requires** to be approved —
- (a) any of the requirements of the Hygiene Regulations is being breached; or
 - (b) inspection under the Hygiene Regulations is being hampered,
- the officer may, by a notice in writing (in these Regulations referred to as a “remedial action notice”) served on the relevant food business operator or duly authorised representative.”

Therefore, RANs can be served on FBOs which have been approved and establishments which are carrying out approvable activities (and so would require approval) but are not yet approved.

Q2.2 Can the FSA advise on specific enforcement action, including the service of notices such as HEPNS and RANS in given circumstances?

A. Whilst the FSA may be able to provide general advice on certain aspects of enforcing the Food Hygiene Regulations, legal opinion/comments on the enforcement and service of individual notices should be sought from LAs own solicitors. This is because each case will vary and the specific detail should be discussed with legal departments within your Local Authority.

Q2.5 An establishment in my area which requires approval for cutting activity by the FSA is acting without approval. Who has enforcement responsibility?

A. The LA will have enforcement responsibility. Until such a time as the premises is approved (in this case by the FSA), the LA has enforcement powers. Section 5.4.2 of the FSA Food Law Code of Practice states that Food Authorities are responsible for enforcement in relation to:

- *Establishments newly subject to approval under Regulation 853/2004 until conditional or full approval is granted, or if approval is refused, by the Agency*

This is also the case where an FBO under FSA control surrenders or has its approval withdrawn by the FSA – enforcement responsibility then lies with the relevant Local Authority

Q2.6 An approved establishment now also wishes to be approved as a cutting plant. Does my authority retain enforcement responsibility for the non-cutting elements or will the FSA take on enforcement for the entire establishment?

A. If the LA-approved Establishment is a meat products or meat preparations establishment, the addition of cutting and supply of fresh meat or slaughter would mean that FSA would take on the approval of the whole establishment – subject

to carrying out an assessment and approval visits of the establishment. LAs should contact the FSA approvals team to discuss any transfers:

approvals@foodstandards.gsi.gov.uk

See also Question 1.7.2 – does the activity need FSA approval?

Any requests for a transfer of enforcement responsibility from the LA to the FSA in cases of approved establishments producing POAO **other than meat or meat products** co-located with cutting plants and/or slaughterhouses need to be assessed on a case by case basis. All cases need to be submitted to the FSA for consideration.

Where the FSA has not taken on enforcement responsibility for all activities undertaken, the LA will be the competent authority (CA) for the activities for POAO other than meat that require approval, whilst FSA will be the CA for the cutting and/or slaughter activities.

Q.2.7 Can I revoke or cancel an establishment's approval where I find serious deficiencies and non-compliances at the establishment during interventions?

A. The words “removing”, “cancelling” or “revoking” an establishment's approval are not terms that appear in legislation. However, where you identify serious deficiencies or repeated non-compliances at an establishment, then Article 31(2) (e) of Regulation (EC) No. 882/2004 requires that you initiate procedures to either suspend or withdraw the approval – depending on whether the FBO can provide adequate assurances that deficiencies will be rectified. The FSA approvals guidance contains more detail on the process to be followed for suspension and withdrawal and also gives examples of what would constitute a “serious deficiency”.