

Guidance on the use of Compliance Notices under the Food (Scotland) Act 2015 (Compliance Notices) Regulations 2023 for breaches of the law on Food Information and Composition Standards

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1. Introduction

The <u>Food (Scotland) Act 2015 (Compliance Notices) Regulations 2023</u> came into force in Scotland on 30 June 2023. These regulations have introduced a new enforcement tool in Scotland called a 'Compliance Notice'. The Compliance Notice has been introduced following the recommendation from the 2013 Scudamore review to introduce a range of new statutory powers to implement effective, robust, and proportionate enforcement of food standards and safety requirements. The regime was set down in the <u>Food (Scotland) Act 2015</u> and is now being implemented in relation to a range of offences.

The Compliance Notice addresses the need for an enforcement tool for Authorised Officers (AOs) to use in dealing with breaches of food information and composition standards legislation. The only formal enforcement options previously available to AOs to deal with any breaches in matters relating to food information and composition standards were to seize and detain product or to submit a report to the Procurator Fiscal (PF) for the breach to be prosecuted as a criminal offence. The process to create and submit a report to the PF is time-consuming for AOs and may not always be a proportionate response to a breach of food standards law. The Compliance Notice is designed to enable AOs to enforce breaches in food information and composition standards without having to submit a report to the PF. This enforcement tool will allow AOs to take a more graduated and proportionate approach to enforcement and is also a more business-friendly approach, to encourage business compliance.

A blank template compliance notice can be found on the <u>FSS website</u>. AOs may choose to use this template or, alternatively, Local Authorities may opt to base their template on this example.

2. What is a compliance notice?

A Compliance Notice is a new enforcement notice for Scotland, designed to operate alongside the existing suite of enforcement notices. A Compliance Notice requires the person upon whom it is served, to take steps to ensure that the person ceases to commit a relevant offence. The relevant offences covered by a Compliance Notice are listed in the schedule of the Food (Scotland) Act 2015 (Compliance Notices) Regulations 2023 and cover food information, food standards, composition and labelling offences.

Further details of Compliance Notice legislative requirements can be found in sections 42-48 of the Food (Scotland) Act 2015.

3. Who can serve a compliance notice?

Compliance Notices may only be served by an Authorised Officer of the appropriate food enforcement authority. To maintain a consistent approach, Food Authorities should only authorise AOs with suitable experience in food law enforcement, and

who are appropriately trained and competent. Such Officers must be either of the following:

- Authorised Officer enforcing food law, food standards or food processing regulations, or
- Holders of the Higher Certificate in Food Standards, Food Control or Food Practice who are authorised to carry out food standards inspections.

The AO who signs the notice must be satisfied that the act or omission constitutes a breach of the relevant Regulations.

4. When can I serve a compliance notice?

4.1 When to use a compliance notice

A compliance notice may be appropriate if a non-compliance meets all of the following criteria:

- Formal action is proportionate to the breach; and
- The AO has confirmed there has been a breach of one of the relevant offences (i.e., those listed in the Schedule to the . A list of which has been provided in Annex B; and
- The AO has reason to believe that an informal approach would not be successful.

4.2 Examples of use

This section provides some examples of when a Compliance Notice may be a suitable enforcement tool. It is intended to provide guidance and is not an exhaustive list. AOs will need to use their own expertise and judgement and take the individual circumstances of the breach into consideration when deciding whether a Compliance Notice is an appropriate tool.

4.2.1 Food information

A Compliance Notice can be used to instruct a business to rectify a non-compliant product label by a suitable means, for example, replacement of the label or overstickering, where a food product is labelled incorrectly and is in breach of a relevant legal requirement. See table 1 for examples below.

Table 1: Examples of when a Compliance Notice might be used to enforce breaches of food labelling legislation.

| Non-compliance | Offence (Domestic Regulation) | Offence (EU Regulation) |
|---|--|--|
| Incomplete or missing mandatory labelling information | Failure to indicate a mandatory list of ingredients as per Reg 10(a) of the Food Information (Scotland) Regulations 2014 | Article 9(1)(b) of FIC provision (1169/2011) (mandatory indication relating to the name of the food) |

| False, ambiguous or misleading health claims on a product label | Breach of Regulation 4 of the Nutrition and Health Claims (Scotland) Regulations 2007 | Breach of Article 3(a) of Regulation 1924/2006 on nutrition and health claims made on foods – general |
|--|--|---|
| Incorrect or missing species or catch area information | Failure to meet minimum labelling requirements for fish products under Art 58(5) of the Fish Labelling (Scotland) Regulations 2013 | principles for all claims 1379/2013 of the European Parliament and of the Council of 11 December 2013 on the common organisation of the markets in fishery and aquaculture products, amending Council |
| | | Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000 (Retained EU Legislation) |
| Incorrect or missing product warnings or information for safe use, e.g. requirement that manufacturers of tabletop sweeteners make available by appropriate means the information necessary to allow safe use by consumers | Regulation 3 of Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013 | Article 23.4 of Regulation 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives |
| Information in incorrect format, e.g. Food Business Operator (FBO) to ensure that mandatory particulars appear on the external packaging in which the prepacked foods are presented for marketing. | Reg 10(a) of the Food Information (Scotland) Regulations 2014 | Article 8(7) (requirement relating to the mandatory particulars required by Articles 9 and 10) of FIC provision (1169/2011) |
| Label not in English on product marketed in Scotland | Reg 10(a) of the Food Information (Scotland) Regulations 2014 | Article 15(1) (language requirements) of FIC provision (1169/2011) |

4.2.2 Compositional standards

If a food product has breached any compositional standards, then a Compliance Notice could be used to require the business to rectify the issue through product reformulation, amendment of processes or removal from the market. For example:

- Composition of the product does not match the details as described on the label.
- The product hasn't met the minimum compositional requirements for the name of that food, or

• The product has exceeded the maximum amount of an ingredient that is allowed in that/a food product.

As proving a breach of compositional standards requires evidence, e.g. lab test results, which can take a matter of weeks to be obtained, it is reasonable to expect that the product in question may already have been sold or be past its period of durability. In this case, the corrective actions specified on the notice should focus on what other actions could reasonably be undertaken by the business in relation to the breach. This may take the form of instructing the FBO to amend a procedure or product formulation.

4.2.3 Novel foods

Only novel foods authorised and included in the GB <u>list</u> may be placed on the market within the United Kingdom as such, or used in or on foods, in accordance with the conditions of use and the labelling requirements specified in the list. A compliance notice could be used in certain situations such as:

• A business placing product on the market not in accordance with conditions of use and the labelling requirements specified in the GB list.

AOs are to note that for breaches of the Novel Foods (Scotland) Regulations 2017, these regulations provide the Novel Foods Detention and Seizure notice as an enforcement tool and it will be up to AOs to determine which notice is most appropriate.

4.3 When using a compliance notice may not be appropriate

A compliance notice may not be appropriate in the following circumstances:

- In transient situations where swift enforcement action is needed, for example, a one-day festival or sporting event. In this scenario, an AO may wish to consider an alternative approach, e.g. seizure and detention of non-compliant product. This is due to the minimum period of compliance of the notice being 14 days. For more information on this please see 'Specified Period' section; or
- Where the breach falls under any hygiene regulations, as defined in Reg 2 of the Food Hygiene (Scotland) Regulations 2006; or
- Where it is not possible to articulate the corrective action(s) which the business must take in order to become compliant, or where the corrective actions stated will not achieve compliance and will only partially address the issue; or
- Where there is a risk to public health as a result of the breach. (See section 5 below); or
- Where the breach is deliberate, or the business has a sustained poor compliance history where more serious enforcement action is likely to be required; or
- Where the breach is a result of fraudulent activity where more serious enforcement action is likely to be required.

Note: In relation to the last two bullet points, a compliance notice may not be suitable where more serious enforcement, such as reporting to the PF may be required because you cannot undertake more than one enforcement action for a single offence, it must be one or the other. If a compliance notice has been served and then an AO decides alternative enforcement would be more appropriate, such as reporting to the PF, the compliance notice should be withdrawn if it is still within the specified period and the business has not already complied with the notice.

5. How do I serve a Compliance Notice?

5.1 Things to consider before serving a Compliance Notice

Before deciding to issue a Compliance Notice:

- 1. Consider whether a Compliance Notice is a suitable enforcement approach.
- 2. Assess whether there is a food safety risk to consumers.
- 3. Take action based on presence/absence of food safety risk to consumers (see Table 2).

Table 2: Enforcement action by risk status

| | Risk | No risk |
|--|--|--|
| Product on market and available to consumers | Address product on market by initiating withdrawal/recall of product (as per 178/2002). A Compliance Notice may be suitable where there are multiple offences associated with the noncompliance, e.g. to address labelling issues. | A Compliance Notice may be suitable. Consider whether action is required for any products that are on the market. If a non-compliant product is to be removed from the market as a suitable corrective action, this can be instructed via the Compliance Notice. |
| Product distributed but not available to consumers | If risk is significant enough to prompt product withdrawal (as per 178/2002), a Compliance Notice can only be used where there is also an additional offence e.g. a labelling breach, as two forms of enforcement cannot be used for the same offence. | A Compliance Notice may be suitable. Consider whether action is required for any products that are on the market. If a non-compliant product is to be removed from the market as a suitable corrective action, this can be instructed via the Compliance Notice |
| Product still within control of business, | Compliance Notice may be suitable. | Compliance Notice may be suitable. |

| i.e. still within | |
|-------------------|--|
| the premises | |
| | |

5.2 Serving a compliance notice

This section deals with the use of Compliance Notices under the Food (Scotland) Act 2015 (Compliance Notices) Regulations 2023 in connection with food standards and composition standards issues.

5.2.1 The enforcement approach

The primary objective of enforcement should always be to achieve compliance in the most effective way possible.

The practices of giving advice and communicating by letter about enforcement issues are well-established approaches to enforcement that are understood by food businesses. Such procedures are, therefore, encouraged whenever they are likely to secure compliance with the requirements of food law within a time that is reasonable in the circumstances.

5.2.2 Service of Notices

The Food (Scotland) Act 2015 (Compliance Notices) Regulations 2023, as per the Food (Scotland) Act 2015 requires a Compliance Notice to be served on a person. Compliance Notices should be served in accordance with the statutory requirements.

A Compliance Notice should be issued for each individual relevant offence. If there are other separate offences for which the Compliance Notice is not appropriate, then separate enforcement measures should be used. For example, if there is a food hygiene issue as well as a food standards issue, then the AO should use a separate hygiene-related notice to address the hygiene matter.

A Compliance Notice must not be served until an offence has been committed. However, it should be noted that even if the food has not left the premises, it can still be considered as having been placed on the market. See the definition of 'placing on the market' (below). In practice, this means that where an offence relates specifically to 'placing on the market', this does not necessarily mean that the product must have physically left the FBO's premises.

Definition of 'placing on the market' as per Article 3(8) of 178/2002 laying down the general principles and requirements of food law:

'Placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves.

If the AO has any doubts that the FBO will comply with the requirement to not place the food on the market and believes that there is a risk of non-compliant product continuing to be sold within the 14-day period, they should consider alternative enforcement action, e.g., seizure and detention of existing stock. The AO should make this decision based on available intelligence about that FBO and their compliance history.

Where it is necessary to prevent the marketing or sale of a non-compliant product due to a food safety risk to consumers, a Compliance Notice may not be a suitable tool given its mandatory 14-day minimum specified period. In the event of a food safety risk confirmed by risk assessment, current withdrawal/recall procedures (as per 178/2002) should be utilised.

It is vital to identify the FBO but if the owner can't be identified at the time of the visit, then the compliance notice can be addressed to the "owner" or "occupier" and delivered to the named premises if the proprietor of the food business cannot be identified.

The main recipient of the Compliance Notice is the food business operator/food business proprietor. The officer serving a compliance notice should ensure, wherever possible, that the person who is responsible for or acting on behalf of the Food Business Establishment also receives a copy, especially where the local manager is not the food business operator/food business proprietor.

A Compliance Notice may be a suitable enforcement tool where a business may be compliant but cannot provide evidence of this. A Compliance Notice would give the business time to provide such evidence. However, this will depend on the nature of the individual offence as it needs to be an issue that can be corrected after the fact, e.g. if the business has not carried out prior notification for an imported product. This cannot be amended retrospectively; therefore a Compliance Notice is unlikely to be suitable.

5.2.3 Drafting of notices

It should be clear from the Compliance Notice exactly what the recipient is required to do, and why. The Compliance Notice should be clearly drafted and easily understood. Visit the FSS website to see an example completed compliance notice. The Compliance Notice should include the following in accordance with s.43(1) of the Food (Scotland) Act 2015:

- a) a statement of the grounds for issuing the notice, including a statement of
 - i. the relevant offence that is alleged to have been committed, and
 - ii. the act or omission giving rising to the offence,
- b) details of the steps that are required to be taken to ensure that the person to whom the notice is issued ceases to commit the relevant offence.
- c) the date of issue of the notice,
- d) the period of time within which the required steps are to be taken,
- e) information about the person to whom, and as to how and by when, any representations about the notice may be made,
- f) information about the right of appeal, including the period of time within which an appeal may be made,

g) an explanation of the effect of complying with the requirements of the notice and of the consequences of failure to comply with those requirements.

AOs should also include the following on the Compliance Notice (note: this is in addition to the legal requirements documented in s.43(1) of the Food (Scotland) Act 2015):

- Identity of the person upon whom the Compliance Notice has been served confirming where the responsibility for compliance lies. This will be the business owner or business representative.
- Name and address of the food business where the offence was identified (the name/address should be as registered with the LA for official purposes). If the Notice relates to a multi-location business, this should be the address of the premises at which the specific offence was committed or where the LA AO identified the issue, as a copy of the Compliance Notice will also be sent to this address (section 2 of the Compliance Notice) and to the head office contact for the food business operator (main address at section 1 of Compliance Notice).
- The signature of the AO.

Serving multiple notices, each with a different specified period, is appropriate where multiple offences have been committed. Multiple notices cannot be served for the same offence, so in cases where more than one notice is served, they must each be dealing with separate relevant offences.

For example, two notices could be served where there is a breach of both 7(1)(a) characteristics of food AND 7(1)(b) attributing proprieties the food does not possess, of the Food Information (Scotland) Regulations 2014.

Separate notices with separate specified periods may also be easier to handle or if there is an appeal. An appeal against a single notice concerning multiple contraventions would result in the suspension of the whole notice until the appeal had been dealt with. Where a notice is partially complied with, it may not be possible to deal effectively with the remaining elements.

5.3 Corrective actions

When an offence has been identified, the AO will inform the business of the all the reasonable corrective actions they need to take to achieve compliance with the specific regulation.

The corrective actions must relate to the specific offence, e.g. where the offence relates to the sale or placing on the market of a product (and there is not a food safety risk to consumers). The AO can include a corrective action to cease the sale and/or marketing of the non-compliant product. However, the FBO will have at least 14 days to implement any corrective actions due to the Compliance Notice's minimum compliance period. The AO will need to use their professional judgement to determine whether the Compliance Notice is a suitable enforcement tool for the non-compliance in question or whether action to cease sale needs to be taken sooner. Such a determination must be based on an assessment of food safety risk to

consumers, in which case alternative enforcement or withdrawal/recall procedures (as per 178/2002) may be more suitable.

Redirection to alternative markets and disposal methods of non-compliant products do not need to be specified on the Compliance Notice within the corrective actions. This level of detail will be a matter for the FBO and the AO to agree upon based on what is feasible and appropriate.

When drafting corrective actions, AOs should ensure that the actions are verifiable, as AOs will later be required to confirm that the steps have been completed and that compliance with the notice has been achieved.

5.4 Specified compliance period

A compliance notice should clearly state the time frame within which the measures/corrective actions required by the Notice must be completed (section 6 of the Compliance Notice). The Food (Scotland) Act 2015 (Compliance Notices) Regulations 2023 specifies a minimum period of 14 days. This can, however, be extended at the discretion of the AO.

An appeal may be lodged against the specified period, so it must be realistic, justifiable, and have regard to the extent and complexity of the measures required.

The specified period should normally be discussed and agreed with the food business operator/ food business proprietor or with a person acting on the operator's/proprietor's behalf who can agree to a specified period before a notice is issued. The AO may, however, set a specified period without agreement if such an agreement cannot be reached or if the person responsible cannot be contacted. The following factors should be taken into consideration in setting a specified period:

- Risk to public health
- Nature of the problem
- Availability of solutions

5.5 Extension of the specified compliance period

Although Compliance Notices are to be complied with within the specified period, Food Authorities should give due regard to any genuine difficulties that may occur in achieving compliance by that deadline.

There is no specific provision in the regulations to extend the specified period for compliance with a notice, but it may be unreasonable not to allow an extension if the food business operator/food business proprietor has a genuine reason for needing more time.

The food business operator should be advised when the notice is served that any request for an extension of the specified period should be made in writing before the notice expires. A Compliance Notice's specified period cannot be extended after it has expired.

If the officer considers the request reasonable, they should note the reasons for their decision on the relevant establishment file. The original notice should then be withdrawn, and a new notice issued and served reflecting the new specified period by which compliance must be achieved. The officer must be aware that any

withdrawn notice is treated as never having existed and so cannot be used as evidence should there be a disagreement later.

An officer should not issue such a new notice without first deliberating upon whether the facts at that time justify such an extension, for example:

- the risk to public health associated with the fault if an extension was granted,
- the reason for the request,
- the remedy involved,
- the past record of co-operation of the operator/proprietor, and
- any temporary action which the operator / proprietor proposes to take to remedy the defect.

Notices should make it clear that the Food (Scotland) Act 2015 allows a food business operator/food business proprietor to carry out measures of at least equivalent effect to those specified in a Compliance Notice. Any alternative measures must be agreed in writing with the officer who served the notice before starting work to avoid unnecessary expenditure or inappropriate work.

The Food Authority should respond in writing to any request from an operator / proprietor to vary the work and any agreed alternative measures should be confirmed in writing.

Disputes should be considered by the Food Authority's lead officer for food safety, or by the head of service or another senior manager.

The Food Authorities should ensure that they have procedures covering such matters, so that it is clear to the operator / proprietor that there is an effective review.

5.6 Monitoring compliance

The officer who served the Compliance Notice should liaise with the food business operator and monitor the work being undertaken and encourage the food business operator/food business proprietor to notify the officer when the work has been completed. Another AO should monitor the work if the officer who served the notice is unable to do so.

The work should be checked as soon as practicable after notification has been received, and the officer should confirm in writing that the work has been satisfactorily completed.

5.7 Appeals

It should be clear to the recipient of a compliance notice that there is a right of appeal against the notice. The notice should therefore include details of the right of appeal. Information on this has been included in the notes of the for your convenience. The AO will also need to provide the recipient with the name and address of the relevant local Sheriff Court.

The food business operator / food business proprietor may be asked to notify the officer if an appeal is lodged; however, there is no obligation to do so in law. The compliance period is suspended upon appeal pending the Sheriff's decision.

6. Using a Compliance Notice when there is a food safety risk to public health

The process of removing a non-compliant product from the market will vary depending upon the presence and nature of risk to consumers.

6.1 No risk, negligible risk or low risk to consumers

Where a product is non-compliant and an offence has been committed, i.e., by the sale of the product, but the risk assessment deems there to be no significant risk to consumers, the AO can instruct the FBO to remove the non-compliant product from the market by a Compliance Notice.

The enforcement action must be relevant to the breach, e.g. where the offence is the placing of the product on the market. The Compliance Notice will instruct the FBO to remove the product and the business will have the specified compliance period to provide evidence that they have undertaken all reasonable steps to remove the product from the market.

If the AO has any doubts that the business will comply with the requirement to cease sale and that there is a risk of the non-compliant product continuing to be placed upon the market within the Compliance Notice's 14-day specified period, then they should consider alternative enforcement, e.g. seizure and detention of existing stock. The AO should make this decision based on available intelligence about that FBO and their compliance history.

6.2 Significant risk to consumers

Where there is a food safety risk to consumers, a compliance notice **would not** be a suitable enforcement tool as the notice would confer a 14-day compliance period. This would be incongruent with the interests of consumer safety. In such an instance, the product will need to be recalled or withdrawn as a matter of urgency. In the event of a food safety risk confirmed by risk assessment, current withdrawal/recall procedures should be used (as per 178/2002).

Where there have been previous offences or non-compliance with previous notices, the AO should consider reporting the FBO to the PF.

6.3 Allergens

The presence of undeclared allergens within a product is likely to present a significant food safety risk to consumers and requires more urgent action than the 14-day minimum permitted compliance period that the Compliance Notice allows. Consequently, an AO will need to consider carefully whether a Compliance Notice is a suitable tool for scenarios involving undeclared allergens. In reality, a Compliance

Notice is unlikely to be an appropriate enforcement tool where there is a significant risk to consumer safety.

In relation to pre-packed for direct sale (PPDS) requirements there are two scenarios for enforcement:

- 1. **Product already available to consumers**: Where there has been a breach of Article 9(1)(c) of Retained EU Regulation 1169/2011 (Provisions of Food Information to Consumers (FIC)) and the product is already on the market and available to consumers, a product recall is likely to be proportionate.
 - Once an AO has instructed a product recall (as per 178/2002) in relation to the breach, the AO cannot also serve a compliance notice for the same offence. However, if the breach has resulted in multiple offences, e.g. a breach of Article 9(1)(c) AND Article 6 Basic Requirement, a product recall can be undertaken for the breach of Article 9(1)(c) and a compliance notice can be served to instruct the business to correct their labelling under Article 6. Other specified FIC provisions that may apply are (these are examples, not an exhaustive list):
 - Article 8(2) (requirement for a food business operator to ensure the presence and accuracy of food information)
 - Article 8(5) (obligation to ensure and verify compliance with food information law etc.)
 - Article 12(1) (availability and placement of mandatory food information)
 - Article 21(1) (requirements relating to certain substances or products that cause an allergy or intolerance)
- 2. Product not yet available to consumers: Where there has been a breach of Article 9(1)(c) of Retained EU Regulation 1169/2011 (Provisions of Food Information to Consumers (FIC)) and the product is not on the market and, therefore, not available to consumers, AOs can instruct amendment of the product label via a Compliance Notice by listing this as one of the corrective actions for addressing a breach of Article 9(1)(c).

7. Relevant specific guidance

7.1 The Food for Specific Groups (Scotland) Regulations 2016

For breaches of this regulation, the AO will need to take into consideration whether this could be a product upon which a consumer or consumer group is dependent. The AO will need to consider whether there are likely to be any unintended consequences of removing access to these products for those who require them, particularly if the product has been developed specifically for an individual or group of people reliant on such a product.

7.2 The Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020 Articles of Retained EU 1169/2011

In relation to Articles 9(1), (2) and (3), a Compliance Notice could be used to instruct the FBO to relabel the product or to rework the formula to comply with a "lactose free" claim. The AO will need to make a judgement based on the potential safety risk from the product, e.g. if the label is to provide a warning for those babies who could be adversely affected by those ingredients - allergic/adverse reactions being potentially fatal in such cases. If the statement is completely missing for lactose, then a Compliance Notice may not be suitable, and the breach would need to be enforced through traditional recall/withdrawal procedures.

In relation to Article 12 (notification requirements), a reasonable period for notification would be a minimum of 14 days.

7.3 The Genetically Modified Food (Scotland) Regulations 2004

In relation to Article 4(2), which prohibits placing food on the market unless it is covered by an authorisation and satisfies relevant conditions of the authorisation, use of a Compliance Notice will depend on the individual situation. Consideration should be given to business awareness/intention. Such FBOs should be aware that they are subject to a specific legislative regime and must not place unlawful goods on the market. Ignorance of the legislative requirements on the part of the FBO is not an acceptable excuse and places other compliant businesses at a competitive disadvantage. It should be noted, however, that a Compliance Notice may be considered suitable for products already on the market where, for example, the product has been authorised in the EU, but it hasn't been authorised in GB yet, i.e. it shouldn't be on the market but is not a particular risk as it has been safety-assessed, albeit not by GB.

In relation to Article 9(3), unauthorised products are not permitted to be placed on the market or to remain on the market once discovered. However, a Compliance Notice could be deemed suitable where there is no proven risk to consumers or if the product is authorised elsewhere. This does not mean that the product should remain on the market, merely that there is scope for the use of a Compliance Notice with a minimum 14-day compliance period.

Appendix A: Example scenarios where service of a Compliance Notice is appropriate

This is an annex to be used for additional information to support the contents of the report. The following scenarios provide examples of where a Compliance Notice should be used. Officers should consider the relevant information and determine the nature of any other necessary actions associated with the service of the Compliance Notice.

Scenario 1

No safety risk. Product out with control of the FBO, i.e. is on the market and available to consumers.

Example: Breach of Regulation 4 of the Nutrition and Health Claims (Scotland) Regulations 2007. Specifically breach of Article 3(a) of Regulation 1924/2006 on nutrition and health claims made on foods.

Article 3 General principles for all claims

Nutrition and health claims may be used in the labelling, presentation and advertising of foods placed on the market [...]1 only if they comply with the provisions of this Regulation.

Without prejudice to [Regulation (EU) No 1169/2011 and the Business Protection from Misleading Marketing Regulations 20083]2, the use of nutrition and health claims shall not:

(a) be false, ambiguous or misleading;

Issue: A consumer has complained about the misleading health claim on Business B's product. An AO investigates and verifies that the claim is non-compliant as the business cannot provide evidence to justify it. The product is distributed UK- wide and is on sale in several large retailers. There is no known safety risk to consumers, but the product is clearly non-compliant.

Scenario 2

No safety risk. Product distributed to other businesses. Not on the market and not available to consumers.

Example: Breach of Reg 5 of the Food Supplements (Scotland) Regulations 2003 - Prohibitions on sale relating to composition of food supplements. Specifically, Reg. 5(1)(b)(ii):

- 5.— Prohibitions on sale relating to composition of food supplements
- (1) [No]1 person shall sell a food supplement in the manufacture of which a vitamin or mineral has been used unless that vitamin or mineral—
- (a) is listed in [schedule 1 of the 2019 Regulations]2; and
- (b) is in a form which-
- (i) is listed in [schedule 2 of the 2019 Regulations]3; and
- (ii) meets the relevant purity criteria.

Issue: Food supplement is being sold by Supplier A. Upon inspection by the AO, the

product is found to be in breach of prohibitions on composition for food supplements because it fails to satisfy the required purity criteria for the contained Vitamin C. The product has been distributed to downstream businesses X, Y and Z who sell this product to consumers.

Scenario 3

No safety risk. Product still fully within the control of the FBO.

Example: Breach of Article 13(1) of Retained EU Regulation 1169/2011 (Provisions of Food Information to Consumers (FIC)) (general requirement for the presentation of mandatory particulars).

Issue: An AO identifies a product at a manufacturer with a non-compliant label where the mandatory particulars are present but are obscured and made illegible by the underlying image and logo on the label.

Scenario 4

Potential safety risk. Product still fully within the control of the FBO.

Example: Breach of Article 3(1) of Retained Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (Retained EU Legislation) (requirement that only vitamins or minerals listed in Annex I and in form listed in Annex II may be added to food), as per Regulation 4 of the Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007.

Issue: Non-permitted (i.e. not listed in Annex A of 1925/2006) vitamins are found to have been added to the food item on the FBO premises.

Scenario 5

Potential safety risk. Product distributed to other businesses. Not yet available to consumers.

Example: Breach of Regulation 6(1) Treatments and additions for natural mineral water of the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007.

Issue: Natural mineral water subjected to treatment other than those listed as permitted in the Regs. Uncertainty around product safety.

Scenario 6

A scenario where you would use the General Food Regulations 2004.

Example: Breach of Article 19 of Retained EU Regulation 178/2002 which is an offence under Reg 4 of the General Food Regs 2004.

Issue: Where an FBO has reason to believe that food they've produced is not in compliance with the food safety requirements (Article 19(1)), they shall withdraw the product from the market and recall from consumers (where it has reached the market) and inform the CA.

If an FBO is found to have not complied with any element of this requirement, due to lack of ability or understanding or genuine error, a Compliance Notice could be used to prevent further offences by ensuring that the FBO put in place appropriate processes and procedures to facilitate an efficient withdrawal/recall process in the future.

If the failure to initiate a recall or withdrawal is found to be deliberate negligence, then a report to the PF would be the better enforcement route. If a situation arises where there is a food safety issue. Then the AO should take the standard approach to initiating a product recall and contact FSS. As there is a minimum timescale of 14 days for the Compliance Notice to be complied with, it would be more appropriate to use the normal product recall procedure to have the non-compliant food product removed from the market more quickly.

Scenario 7

A food business, Street Gourmet Takeaway, owned by Wessex High Street Foods Limited, retails a small quantity of Pre-packed for Direct Sale (PPDS) food products. The Street Gourmet purchases whole fillets of Smoked Trout and Smoked Salmon from a local smokehouse, then portions, re-packages and labels the fillets, and places them in the display chill for sale.

An AO took a sample of a product described as 'Smoked Salmon' which was identified through laboratory testing as 'eritque arcus tructa', commonly known as Rainbow Trout, not Salmon.

Issue: The smoked salmon fails to comply with Reg 5(1) of the Fish Labelling (Scotland) Regulations 2013, specifically Article 35 paragraph 1 (a) (as read with Art. 38) of Retained Regulation [EU] 1379/2013 on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000

Article 35 Mandatory information

- 1. Without prejudice to Regulation (EU) No 1169/2011, fishery and aquaculture products referred to in points (a), (b), (c) and (e) of Annex I to this Regulation which are marketed [in the United Kingdom], irrespective of their origin or of their marketing method, may be offered for sale to the final consumer or to a mass caterer only if appropriate marking or labelling indicates:
 - (a) the commercial designation of the species and its scientific name;

Scenario 8

Following on from Scenario 7, the label for the Street Gourmet's re-packaged Smoked Salmon advertises the product as 'Smoked Salmon' as does the Consumer Information Board on the wall displayed in the business. On further examination the AO discovers there are no details of the provenance (farmed area) of the 'Smoked Salmon' on the packaging.

Issue: This would be a failure to comply with Reg 5(1) of the Fish Labelling (Scotland) Regulations 2013, specifically Article 35 paragraph 1 (c) of Retained Regulation [EU] 1379/2013 on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000.

Article 35 Mandatory information

- 1. Without prejudice to Regulation (EU) No 1169/2011, fishery and aquaculture products referred to in points (a), (b), (c) and (e) of Annex I to this Regulation which are marketed [in the United Kingdom], irrespective of their origin or of their marketing method, may be offered for sale to the final consumer or to a mass caterer only if appropriate marking or labelling indicates:
 - c) the area where the product was caught or farmed, and the category of fishing gear used in capture of fisheries, as laid down in the first column of Annex III to this Regulation;

Appendix B: Example scenarios where service of a Compliance Notice is not appropriate

Scenario 1

Potential safety risk. Product out with control of the FBO, i.e. is on the market and available to consumers.

Example: Breach of Reg 10(3) Limits for lead and cadmium and declaration of compliance, as per Reg 19(1) of the Materials and Articles in Contact with Food (Scotland) Regulations 2012.

Issue: Following random testing by LA as part of the FSS Sampling Grants programme, a set of salad tongs available for sale at a small retailer in Scotland is found to contain lead above the permitted levels. Investigation shows that the product is manufactured by Manufacturer A and has been imported from China and has been distributed nationally.

As this scenario involves national distribution, there is little benefit to using a Compliance Notice. It would be more appropriate for this matter to be reported to FSS as an incident and handled via the normal incident management channels. A risk assessment would be undertaken to determine whether withdrawal/recall were proportionate and to determine the risk management for the incident.