

Updated FSA Official Control Compliance Framework for Registered Dairy Establishments in England and Wales

Launch date: 12th December 2022

Respond by: 10th March 2023

This consultation will be of most interest to

- Registered dairy establishments in England and Wales
- Raw milk processors
- Dairy/milk trade organisations
- Consumers of dairy products
- Enforcement authorities

Purpose of the consultation

To provide interested parties with the opportunity to comment on:

- Proposed changes to how final compliance ratings are applied following primary production Official Control (OC) inspections completed by the Food Standards Agency (FSA) at registered dairy establishments in England and Wales
- 2) Subsequent use of a new risk rating framework with additional inspections for higher risk establishments.

How to respond

Responses to this consultation should be sent to <u>dairyops@food.gov.uk</u>

Details of consultation

List of abbreviations and acronyms used in this consultation

- FBO Food Business Operator
- OC Official Controls
- FSA Food Standards Agency
- RCDM Raw Cows Drinking Milk for direct supply to the final consumer
- RTFA Red Tractor Farm Assurance
- NI Northern Ireland
- FSS Food Standards Scotland

Introduction

A review was recently commissioned and completed by the FSA to assess the programmed frequencies applied to OC inspections at registered dairy establishments in England and Wales. OC inspections are undertaken to ensure that businesses are compliant with the requirements of the legislation designed to protect consumers and to ensure food is safe are being met.

The existing risk rating framework has been in place since 2012, the review was seeking assurances that this approach is still relevant and fit for purpose.

The review considered the frequencies of programmed OC inspections undertaken by the FSA at registered dairy primary production establishments in England and Wales. The review did not include any other OC activities undertaken by the FSA or other agencies in relation to food, feed or animal welfare.

All recommendations made following the review and detailed within this consultation are a proposed change to FSA policy, that requires no changes to legislation.

Background

A working group of key stakeholders was established to provide a balanced and consistent approach and review the current inspection frequencies. This group consisted of representation from across the FSA and Food Standards Scotland (FSS). The review concluded that the current system of utilising assurance schemes, (Red Tractor Farm Assurance (RTFA) for dairy in England, Wales and Northern Ireland), to manage conformance to their standards and periodically report to FSA on the findings of their own

audit outcomes provides an adequate level of assurance. This in turn permits members of the RTFA dairy scheme to benefit from "earned recognition" allowing for FSA OC inspections at these premises to be less frequent if they remain compliant with the assurance scheme standards.

Furthermore, the evidence and data showed that, in the main, the current routine inspection frequencies applied at all registered farms was deemed to be satisfactory and proportionate

However, it was noted that some improvements could be made to how FSA ensures that premises that are found to be non-compliant regain compliance and maintain the expected standards.

Main proposals:

The FSA is proposing to adjust the risk rating framework used to assess compliance and determine frequency of OC inspection undertaken by the FSA at registered dairy establishments. The FSA intends to introduce an increased frequency of OC inspection at establishments assessed to be less compliant.

We will do this by:

- Introducing a numerical scoring system which weights areas of greater significance/impact (areas with stronger links to public health/animal welfare) and use of the overall score achieved to determine risk rating categories
- Replacing the existing four compliance categories with three score rating categories which focus on risk.
- Using the risk category applied following inspections to determine the frequency of the next programmed OC inspection for that premise. This prioritises FSA resource at businesses that are found to be least compliant and therefore higher risk

Current Approach

Currently, following completion of the OC inspection by FSA a compliance rating is applied and this will see farms achieve one of 4 levels of overall compliance. Good, Generally Satisfactory, Improvement Necessary or Urgent Improvement Necessary. A framework exists with guidance on considerations to be made by the inspectors before deciding on which compliance level to apply depending on what they witness during the inspection, but this framework leaves significant room for human interpretation. Whilst a level of interpretation is important it was recognised that a more structured framework will provide improved consistency of approach. Current compliance levels also do not have any influence on the next OC inspection frequency and once any/all non-compliances have been rectified the premise returns to its original inspection frequency (10 yearly, 2 yearly or 6 monthly).

Detailed Proposals

It was therefore recommended to adopt a new and revised compliance rating framework using a numerical scoring system with scores weighted in areas deemed of greater significance/impact with the overall final score providing the risk rating for each farm based on the findings of the most recent FSA OC inspection.

The proposed version of the scoring system which highlights the areas deemed to be of greater impact and therefore with higher scores along with the proposed additional inspection frequencies can be found at **Annex A**.

The DHI will conduct their inspection, reviewing each section in accordance with the subheadings down the left-hand side of the scoring table included at **Annex A**. They will be provided with guidance on factors to consider when applying the score for each of these sections and will score them appropriately.

On completion of the inspection an overall score will be calculated using the total of the sub-heading scores, this will place the establishment into one of 3 overall risk rating categories (low, medium or high). The final risk rating applied will determine the frequency of the next routine FSA OC inspection. All future routine inspection frequencies will then be determined by the outcome/rating achieved during the previous routine inspection and the risk category that the premise falls into.

Adopting this approach allows FSA resources to be more targeted towards less compliant businesses.

As there are no proposed changes to legislation, changes to the enforcement action of any non-compliances identified are outside of the scope of this proposal. The FSA will continue to apply our existing approach to any enforcement required.

Premises producing Raw Cows Drinking Milk (RCDM) for direct supply to final consumer are subject to FSA verification sampling at the same time as their routine 6 monthly inspection (at least twice per year). If additional inspections are applied due to noncompliances, this does not mean they will automatically come with additional sampling at a cost to the FBO. If additional sampling is considered necessary, it will be discussed clearly with the FBO at the time.

The proposed changes are only applicable to the compliance framework for FSA OCs at primary production. The delivery of OC activities by other agencies is outside of the scope of this consultation.

Impacts

The proposed changes to the compliance framework will not include any changes to legislation, so this consultation does not include a Regulatory Impact Assessment. In line with best practice, FSA has considered the potential costs and benefits that stakeholders including FSA, local authorities and industry, may experience as a result of the proposed changes. Details of the costs and benefits considered are summarised below.

Number of registered primary production dairy premises in England and Wales

As of November 2022, there are 6,379 wholesale-only milk premises and 127 Raw Drinking Milk (RDM) registered premises in England. Of those 127 RDM premises, 106 also produce milk for wholesale. In Wales, there are 1,512 wholesale-only milk premises and 9 RDM registered premises. All 9 RDM producers also produce milk for wholesale.

In the current model, if major non-compliances are found, the premises has a follow-up inspection. If rectified, they move back to their previous inspection frequency, which will either be every 6 months (if producing RDM), every 2 years or every 10 years (If they are members of the Red Tractor Dairy Assurance Scheme).

The proposed model will consider the severity of non-compliances found using a risk rating scoring system found in Annex B, which will determine the inspection frequency going forward.

The dairy inspections included within the scope of this consultation and Impact Assessment (IA) are undertaken by FSA, so there will be no impact on local authorities.

Cost to industry

The proposed policy change will initially require RDM and wholesale milk producers to understand the new frequency of inspections. We assume that one manager per premises will take 1 hour familiarising themselves with the changes. To this, we apply a median hourly pay for managers of $\pounds 26.56^1$ (after accounting for overheads) to give a total one-off familiarisation cost for all dairy premises of $\pounds 172,795.46$ in England and $\pounds 40,396.85$ in Wales.

The proposed compliance framework model will change the frequency of the Official Control Primary Production Inspections to prioritise FSA resource towards the most noncompliant premises.

¹ Taken from the Annual Survey of Hours and Earnings 2022. More details can be found here: <u>https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/annualsurveyofhoursandearningsasheguidetotables</u>

An increased number of inspections will result in a time cost for non-compliant premises to deal with the additional inspections. Compliant premises will continue to be inspected at their current routine frequency of either 10 yearly, 2 yearly or 6 monthly, in line with their level of risk.

FSA do not charge premises for dairy inspections. Premises producing RCDM are subject to FSA verification sampling at their usual 6 monthly inspection. It is assumed that no additional sampling will be taken by the FSA because of this policy and therefore there will be no increased enforcement costs to industry.

Costs to FSA

The proposed changes to the compliance framework will impact the day-to-day role of FSA's Dairy Hygiene Inspectors requiring them to read and understand the changes. This will be disseminated in a one-off training event estimated to take no longer than one working day per inspector. We assume a 7.5 hour working day and multiply this by an hourly wage of £20.81 (after uplifting for overheads). FSA currently employ 24 DHI's leading to a cost of time for training of £3,745.80. This will then form part of a typical DHI's induction materials so additional ongoing training costs will be negligible. We expect one Higher Executive Officer (HEO) grade FSA member of staff to prepare the material and deliver the training over 2 days. We have taken the average monthly salary of HEO grade staff and divided by 20 to calculate the cost per working day. Taking this value and multiplying by 2, for the number of days taken, we estimate the training delivery cost to the FSA to be £366.00. As the training will either take place online or in an FSA building, we expect the venue cost of training to be zero. Collectively this will lead to an overall training cost of £4,112.

The change to the compliance framework is likely to lead to an initial increase in inspections for non-compliant premises, though this increase is expected to be small in the dairy industry, where only 0.2% of premises in England and 0.1% in Wales fall into the 'Urgent improvement necessary' category. Dairy businesses are not charged for inspections, so the initial cost of enforcement relates to the time taken for additional inspections for FSA. One third of DHI's complete dairy work on a full- time basis, whilst the remaining two thirds are FSA employed Meat Hygiene Inspectors (MHI's) whose roles will need to be backfilled when they are released periodically to support with dairy inspections which may increase the overall cost to FSA. The initial increase in enforcement costs and the longer-term trend is difficult to estimate precisely, as the frequency of inspections will depend on business behaviour and the result of their most recent inspection. We therefore estimate the impact of the first inspection as an illustration of the maximum cost per annum for the first 2 years.

We assume that each additional inspection takes on average one hour per DHI (or MHI), with an hourly wage of £20.81 (uplifted for overheads). Calculating the costs precisely is not possible but we can estimate working on some assumptions. The change will lead to an increased number of inspections, certainly at first, and we expect this could be up to

£50,000 across 2 years, if all the currently non-compliant premises were to receive an additional inspection before they reached compliance. This assumes all premises that currently fall in to the 'Generally satisfactory', 'Improvement Necessary' and 'Urgent Improvement Necessary' categories (Around 2500 premises) could receive at least one additional inspection over the first two-years.

Longer-term cost predictions are much harder to make as they rely on understanding what levels of compliance might be found at farms that could be inspected after this 2 year period, however, because the new framework should make it easier for dairy business to maintain compliance, it's not unreasonable to think that any additional inspections required through non-compliance will reduce, and eventually, could fall to being a consistent, low number. Possibly a lower number than there is currently.

There is an expected technology cost for the development of a dairy app to record inspection findings and risk level. This is part of a wider FSA programme for digitalisation, in which the dairy app will form a minor part of the overall process; we expect the cost related solely to the dairy frequency of inspections to be minimal.

The inspection frequency change is specific to dairy inspections enforced by FSA. Other official controls are out of the scope of this proposal so there will be no additional impact on local authorities.

<u>Benefits</u>

Three main benefits are expected as a result of the adoption of the new inspection frequencies:

- greater clarity for dairy premises in terms of how they have been assessed and how to return to compliance, ultimately leading to reduced costs of compliance
- increased level of trust and confidence in the dairy industry, as non-compliant dairy businesses will now be inspected more frequently
- reduced likelihood of a foodborne disease outbreak from RDM.

Greater clarity for dairy businesses

Within the compliance framework the risk rating applies a numerical scoring system that DHIs will use as part of their routine inspections. Scores are weighted, placing more emphasis on higher risk areas linked to both hygiene and animal welfare. This is an improvement on the current system, where dairy premises are given a risk-rating based primarily on the activities undertaken at the premises. Once the inspection is complete, an overall score is calculated, and the premises will fall into one of three different risk categories, Green, Amber and Red. If the premises is rated as Amber (medium risk) or Red (high-risk), then more frequent inspections are applied outside of the routine cycle.

Whilst Inspectors have some guidelines to follow under the current arrangements, these still leave a lot of room for human interpretation, which can lead to inconsistencies. A lack of consistency when it comes to the FSA's advice, recommendations or judgement can prove problematic for businesses, particularly if some investment is required to resolve any issues. For example, there is potential under the current model for a business to receive different feedback in two different inspections, even though nothing has changed in between.²

Whilst it is neither possible nor desirable to remove the need for human interpretation entirely, the numerical scoring system does provide more structure for the DHIs to follow. As a result, dairy businesses will be able to get a better understanding of how their score is compiled, how this has led to their overall rating and how improving their score in certain areas will help to improve their rating.

This additional clarity will help dairy premises to both become and stay compliant more efficiently. It allows them to target their resources and investments more effectively, in the knowledge that there will be a consistent approach to inspections and the investment is warranted. Ultimately, this will reduce the costs of compliance.

Increased trust and confidence in the dairy industry

As a result of the proposed changes, any dairy premises that are rated Amber or Red will be inspected more frequently, outside of their routine cycle. Furthermore, a full reinspection will take place and a new score generated. Under the current arrangements, a re-inspection only focuses on those areas that were found to be non-compliant in the previous inspection. It is envisaged that this approach will lead to improved consistency of compliance.

The targeting of resources towards premises with a higher risk rating, coupled with increased clarity for dairy businesses as to their level of compliance, is expected to lead to an increased level of trust and confidence in the dairy industry, from consumers and other stakeholders.

This increased level of trust will support the long-term economic growth of the sector, by reducing the likelihood of a foodborne disease outbreak and signalling to consumers and other stakeholders that dairy hygiene is taken seriously

Potential to reduce likelihood of a foodborne disease outbreak from RDM

Currently, premises producing RDM are deemed high-risk and as such, are on a sixmonthly inspection cycle. Under the proposed arrangements, RDM farms classified as

²See <u>https://www.food.gov.uk/research/behaviour-and-perception/fsa-and-official-controls-research-with-food-business-operators</u>

'Red' will be inspected again within two months. Those classified as 'Amber' will be inspected again four months after their latest inspection. Those rated as 'Green' will remain on the current six-monthly inspection cycle.

The more frequent, risk-based, full re-inspections proposed could contribute to reducing the likelihood of a foodborne disease outbreak linked to RDM.

Raw milk can carry dangerous bacteria such as Salmonella, E. coli, Listeria, Campylobacter, and others that cause foodborne illness. The FSA's Cost of Illness model³ provides estimates of the burden of foodborne disease in the UK, which can be used to estimate the benefits (or costs avoided) from any actions that reduce foodborne disease incidents.

The following gives an illustration of the potential costs of illness that could be avoided, as a result of the increased inspection frequencies.

According to a study by Public Health England⁴, there were four foodborne disease outbreaks recorded in 2017 that were linked to RDM, with thirty-five cases in total (27 from campylobacter, 1 from salmonella and 7 from shigella). According to the FSA's Cost of Illness Model, if these thirty-five cases had occurred in 2022, the cost to society would have been around £140,000.

It is difficult to know precisely how many foodborne disease cases linked to RDM will be prevented as a result of the change in inspection frequencies for farms that produce it. However, the cost of illness figures suggest that the benefits of prevention are likely to outweigh the costs of doing so, over the medium to long-term.

Engagement and Consultation Process

The proposed changes have been developed using a multi-stakeholder working group approach.

Engagement meetings have taken place with the following. Dairy UK, Red Tractor and the Raw Milk Producers Association, at these meetings the proposed revised compliance

⁴ <u>Gastrointestinal infections caused by consumption of raw drinking milk in England & Wales,</u> <u>1992–2017 - PMC (nih.gov)</u>

³ The results of which are published, here <u>https://www.food.gov.uk/research/foodborne-disease/the-burden-of-foodborne-disease-in-the-uk-2018-0</u>

framework was presented. The proposed new approach was welcomed as a positive step and supported by these organisations.

Following completion of the 12-week consultation all responses will be collated and responded to, these responses will also be published.

Responses

Responses are required by close Friday 12th February 2023 Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Please send response to dairyops@food.gov.uk

For information on how the FSA handles your personal data, please refer to the Consultation privacy notice at <u>https://www.food.gov.uk/about-us/privacy-notice-consultations</u>'.

Further information

If you require a more accessible format of this document please send details to the named contact for responses to this consultation and your request will be considered.

This consultation has been prepared in accordance with <u>HM Government consultation</u> <u>principles</u>.

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Colin Thompson

Dairy Operational Lead

Dairy Operations

Annex A: Draft of proposed Compliance Framework scoring system and revised inspection frequencies

DAIRY INSPECTION ASSESSMENT REPORT			
Wash-Room, Milk Storage & Collection			
Approach & Surrounds	0	2	4
Doors/Walls, /Storerooms & Structure	0	2	4
General Hygiene & Management	0	4	8
Total (out of 16)			L
Milking & Cooling Equipment			
Cleanliness of Milk Tanks & Equipment	0	5	10
Cleaning Processes & Recording	0	4	8
Total (out of 18)			
Milking Operations			
Teat Preparation	0	4	8
Operator Hygiene & Cleaning	0	4	8
Detection of Abnormal Milk & Rejection	0	5	10
General Hygiene & Structure	0	4	8
Veterinary Medicines	0	3	6

Total (out of 40)			
Animal Welfare			
Animal Cleanliness & Health	0	5	10
Access Routes, Housing, Feeding, Grazing	0	2	4
Total (out of 14)			
Pre-requisites			
Water	0	3	6
Vermin Control	0	2	4
Isolation facilities	0	1	2
Total (out of 12)			
Total 100			

Risk categories and inspection intervals:

Non RDM and member of dairy assurance

Score	Risk Category	Interval
71-100	Red	< 6 months
17-70	Amber	< 2 years
0-16	Green	< 10 years

Non RDM and not a member of dairy assurance

Score	Risk Category	Interval
71-100	Red	< 3 months
17-70	Amber	< 1 years
0-16	Green	< 2 years

<u>RDM</u>

Score	Risk Category	Interval
71-100	Red	< 2 months
17-70	Amber	< 4 months
0-16	Green	< 6 months