

Regulator Assessment: Qualifying Regulatory Provisions

Title of proposal	FSA Business Guidance
Lead Regulator	The Food Standards Agency
Contact for enquiries	Chris Harvey

Date of assessment	18 April 2017
Commencement date	August 2015
Origin	Domestic/EU
Does this include implementation of a Cutting Red Tape review?	N/A
Which areas of the UK will be affected?	England

Brief outline of proposed new or amended regulatory activity

[N. B. The following assessment relates to two separate Guidance documents, individually assessed and scored under the Business Impact Target (BIT), but presented in a combined BIT Regulator Assessment for ease and reduced burden.

Between May 2015 and May 17 the FSA published two guidance documents that qualified as regulatory provisions under the BIT. Both guidance documents were produced to provide advice to business on areas of directly applicable EU regulations where specific non-compliance was identified.

- The ***Information and guidance on the testing of milk for antibiotic residues*** was updated by the FSA in August 2015 to provide additional advice on risk-based sampling. The update was in direct response to EU Food and Veterinary Office (FVO) audit findings in 2013, that identified failings with UK dairy hygiene controls in relation to the UK approach to antibiotic testing. The FSA estimated that approximately 6% of the guidance document was changed to incorporate the clarification required to update the guidance including routine non-material amendments to simplify text and correct inaccuracies. Overall, the updated guidance now presents a slightly reduced familiarisation burden.
- The ***Guidance for healthcare and social care organisations on reducing the risk of vulnerable groups contracting listeriosis*** was produced by the FSA in close collaboration with business, health and social care stakeholders. The guidance was deemed necessary to help reduce the risk of vulnerable people within care settings from contracting listeriosis, following continued outbreaks of listeriosis in healthcare organisations involving ready-to-eat foods. The guidance provides advice on the legal requirements of food safety and hygiene legislation and includes clearly identified examples of good practice to help health/social care organisations determine what practical steps can be put in place to help them reduce the risk of vulnerable people within their care contracting listeriosis

Though both guidance documents provide advice on directly applicable EU regulation, neither were produced in response to new or amended EU regulations and are therefore Qualifying Regulatory Provisions within scope of the BIT.

Which type of business will be affected? How many are estimated to be affected?

The **Information and guidance on the testing of milk for antibiotic residues** is intended for businesses throughout milk production chain including farmers, milk purchasers and processors and will range from micro enterprises to large scale production establishments. The FSA has strong internal data (**Annex A**) to draw on, identifying the **1037 establishments** approved for collecting or processing milk and **7752 registered producers**

The **Guidance for healthcare and social care organisations on reducing the risk of vulnerable groups contracting listeriosis** will be of interest to health care setting that routinely provide ready to eat food for vulnerable people i.e. hospitals and residential care/nursing homes.

Establishing the businesses affected by this guidance has been more difficult due to the way in which FSA data is categorised for this sector (**Annex B**). However, using Care Quality Commission (CQC) data¹ the FSA has identified **approximately 25,000 care providers** that are likely to be within the target audience for this guidance.

Summary of costs and benefits

Price base year	Implementation date	Duration of policy (years)	Net Present Value	Business Net Present Value	Net cost to business (EANDCB)	BIT score
2016	2017	10	-0.16	-0.16	0	0

Please set out the impact to business clearly with a breakdown of costs and benefits

Both guidance documents were produced by the FSA directly in response to identified business non-compliance with directly applicable EU regulations. Though the Listeriosis guidance incorporates basic good practice examples (e.g. *hand washing and wearing clean clothes* etc.) to help businesses to identify approaches that will help them meet the requirements of EU legislation, all good practice examples are clearly identified as being good practice, not legal requirements. Neither document therefore place any stated or implied requirements on business beyond the directly applicable minimum EU requirements.

The FSA has determined therefore that both documents present only familiarisation burdens to industry – an assumption that was tested through consultation with stakeholders during development of the guidance and prior to publication of the final document. In both cases, stakeholders did not disagree with the FSA assessment or identify any other burden resulting from the guidance documents. In the case of the **Listeriosis guidance** the Welsh Food Microbiological Forum stated:

- The guidance should be helpful by providing clear guidance to those organisations to which it is aimed, as well as assisting food safety officers during inspections of these types of premises.*
- The document clearly highlights what is considered to be good practice and we welcome the guidance it provides on foods which are brought in by patients and visitors.*

For the **Listeriosis guidance** the FSA have identified a single hourly wage rate² (**£18.29**) for the sector as a whole inclusive of a 20% uprate to account for overheads in line with SCM methodology³. For the **Antibiotic Residues guidance** two separate wage rates were necessary (**£11.96** per hour for producers and **£25.50** per hour for processors - both figures obtained from ASHE incorporating a 20% uplift).

The FSA notes that there are numerous established approaches to assess the familiarisation cost of regulatory guidance, for which each have different strengths and weaknesses. For ease and consistency therefore the FSA have taken a simplified standard approach to identifying the familiarisation cost to business for our routine assessments based on outcomes of the guidance produced by the Cross-Whitehall Group Economics of Regulation using the following assessment criteria:

¹ <http://www.cqc.org.uk/content/how-get-and-re-use-cqc-information-and-data#directory>

² Wage rates were obtained from Annual Survey of Hours and Earnings 2016 (Provisional) and based on 'Health Care Practice Manager' for the Listeriosis guidance and 'Farmers' and 'Production managers and directors in manufacturing' for the Antibiotic Residues guidance.
<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashtable14>

³ SCM methodology <http://www.berr.gov.uk/files/file44503.pdf>

- **EFTEC 2013⁴**: average time to read different type of text (words per minute): **prose 250-300; technical text 50-100**. As the level of complexity of the text in both of these guidance documents is low, a mid-point estimate of 275 words per minute reading time has been used.
- applying a standard assumption for FSA assessments that 54% of the identified business sector size will read the guidance – based on the “**Business Perception Survey (BPS)**”⁵ sector and firm size on the proportion of businesses that “use government websites to find out about how to comply with regulation”.

In addition to the above criteria the FSA has also determined that there should not normally be an ongoing need for businesses to routinely re-familiarise themselves with FSA guidance as any steps they feel are necessary to take as a result of reading the guidance should be integrated into their food safety management systems they are required to have in place. Any re-familiarisation would therefore be entirely a commercial decision by the business.

The FSA believe that this is a proportionate approach to the assessment of routine FSA guidance.

Familiarisation cost of Listeriosis Guidance(one-off, monetised):

There is a familiarisation cost is determined by calculating the expected reading time that each of manager/ supervisor (one for each of the 25,000 relevant health care providers) would spend reading the guidance. The expected reading time per manager/ supervisor is a one-off time cost 0.57 hours⁶ This is then multiplied by the 13,500 figure to account for each health care provider and an hourly, uprated, wage rate of £18.29. The total one-off cost is £140k. This leads to a total net present value to business of -£0.14m for and an EANDCB and BIT score of zero.

Familiarisation cost of Antibiotic Residues Guidance (one-off, monetised):

There is a familiarisation cost is determined by calculating the expected monetised time cost that a manager or director (one for each of the 1,037 processors and 7,752 producers expected to be impacted) spend reading the updated guidance. The expected reading time for each individual is 0.28 hours⁷. This is then multiplied by the number of relevant processors (560) and producers (4,186) and then by their respective uprated wage rates (£25.50 and £11.96 respectively). The total one-off cost is £18k. This leads to a total net present value to business with a net present value to business of -£0.018m for and an EANDCB and BIT score of zero.

The joint total business net present value is -0.16 with an EANDCB and BIT score of zero.

Please provide any additional information (if required) that may assist the RPC to validate the BIT Score

Initial assessment documents were completed by the policy leads for each guidance document, providing the evidence basis for this combined BIT assessment – the assessments are attached at Annex A and B.

⁴ EFTEC (2013), “Evaluating the cost savings to business from revised EA guidance – method paper”

⁵ Business Perception Survey 2014,

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/314378/14-p145-business-survey-2014.pdf

⁶ This is calculated by dividing the total number of words in the guidance document, 9,375 by the number of words that are estimated to be read per minute – 275 – and transforming this to an hourly figure.

⁷ This is calculated by dividing the total number of words in the guidance document, 4,658 (reduced from 4,976) by the number of words that are estimated to be read per minute – 275 – and transforming this to an hourly figure.

STANDARD ASSESSMENT TOOL FOR NEW OR MATERIAL CHANGES TO FSA GUIDANCE

[A pre-requisite for using this form is that guidance is written in plain English, with technical jargon used only for guidance intended for technical audiences]

1. Guidance Title:	Information and guidance on the testing of milk for antibiotic residues.		
2. Is Guidance:	New?		Amended? Yes
3. Purpose of Guidance:	To advise on the implementation of Regulation (EC) No 853/2004 as regards the testing of milk for antibiotic residues. In particular, the requirements at Annex III, Section IX, Chapter I.III.4 that food business operators must initiate procedures to ensure that raw milk is not placed on the market if it contains antibiotic residues in excess of regulated limits.		
4. Rationale for Intervention:	EU Food and Veterinary Office (FVO) audit findings in 2013, of UK dairy hygiene controls, made recommendations for improvements to be made to the UK approach to antibiotic testing. In response to the finding the FSA guidance was revised to provide additional advice on risk-based sampling.		
Is guidance required for new or amended legislation?			No
EU?		Domestic?	Insert link
5. Does the guidance go beyond the requirements of the legislation?*			No
<p>The revision addressed FVO findings that the UK was not fully complying with the EU legislation – the revision focused on</p> <ul style="list-style-type: none"> reporting of 'adverse events', eg where antibiotic test failures have occurred after the withdrawal period clarification of the need for testing of milk from road tankers prior to use of milk in processing establishments clarification of what food business operators need to report to their Competent Authority, eg where milk is tested and failures occur clarification on the sampling and testing frequency and the need for sampling frequencies to be determined on a risk basis. <p>The revision also updated references to Regulations where these have changed and other cosmetic changes such simplifying language and removing unnecessary text to reduce the burden on business.</p>			
6. Does the guidance introduce any new requirements on business (including information requests, mandatory forms etc.) not directly required in law?*			No
As above, the revision incorporated clarified requirements where the FVO had identified under-implementation in the UK approach to EU Regulations.			
7. Intended audience?	Business	Y	Local Authority (LA) Y
8. If LA, is guidance intended to change their regulatory approach or otherwise impact on business?*			N
As above, the guidance update reflected changes to approach required by business. The approach required by LAs to verify compliance has not changed, LA's will however now have a clearer understanding of what constitutes compliance in this area and will act accordingly to identified non-compliance.			
9. If Business, what does the sector look like?			
The guidance is intended for all interested parties along the milk production chain including farmers, milk purchasers and processors and will range from micro enterprises to large scale production establishments.			

All establishments handling liquid milk and dairy products are approved by local authorities and are subject to official controls enforced and executed by local authorities. The FSA published lists of all approved establishments (30 March 2017) records **1037** establishments approved for dairy processing activities or collection centres.

Any producer selling milk for human consumption needs to be registered with the Food Standards Agency and this covers a range of possibilities from someone with 1 goat to 1000 plus dairy cows. As of 31 March 2107 there are **7752** producers registered in England – figures include buffalo, goat and sheep’s milk producers as well as cows’ milk producers.

10. What level of employee will be responsible for familiarisation of the guidance?

Provide assumptions/evidence to identify average salary

11. Average wage rate identified for Dairy Producer (Farmer)?	£9.97ph
updated by 20% to account for overheads in line with SCM methodology ⁸	£11.96ph
Average wage rate identified for Dairy Processing Manager?	£21.25ph
updated by 20% to account for overheads in line with SCM methodology ⁹	£25.50ph
Wage rate obtained from Annual Survey of Hours and Earnings 2016 (Provisional) and based on ‘Farmers’ and ‘Production managers and directors in manufacturing’ which we believe to be the most suitable equivalent position.	

12. What is the guidance total word count?	4967
13. For revised guidance, what % (approx.) has been changed?	6%
A 6% estimate has been given based on the extent of the update, which were made via succinct clarifications to the existing requirements outlined in the guidance. As a result of the update, including the simplification of the information given in the guidance, the document was reduced by 318 characters.	

14. Level of complexity for intended audience	Low
The revised guidance relates to a technical subject but the language used is written in plain English and the information relates to routine activity undertaken by the intended audience, who are very familiar with the subject content.	

15. Any other factors requiring consideration to assess the guidance impact?*	
N/A	

* If ‘Yes’ to Questions 6, 8 or 15 please quantify the assessment of the impact	
N/A	£0.00

⁸ SCM methodology <http://www.berr.gov.uk/files/file44503.pdf>

⁹ SCM methodology <http://www.berr.gov.uk/files/file44503.pdf>

STANDARD ASSESSMENT TOOL FOR NEW OR MATERIAL CHANGES TO FSA GUIDANCE

[A pre-requisite for using this form is that guidance is written in plain English, with technical jargon used only for guidance intended for technical audiences]

1. Guidance Title:	Guidance for healthcare and social care organisations on reducing the risk of vulnerable groups contracting listeriosis
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2. Is Guidance:	New?	Y	Amended?	N
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3. Purpose of Guidance:	The guidance is intended to help health/social care organisations determine what practical steps can be put in place to help them reduce the risk of vulnerable people within their care contracting listeriosis. The guidance provides advice on the legal requirements of food safety and hygiene legislation and includes examples of good practice. The guidance is applicable only to ready-to-eat foods, although following good practice in the guidance will help to reduce risks for other foods and will reduce the risks for other foodborne pathogens.
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4. Rationale for Intervention:	The guidance was produced as part of the Food Standards Agency's programme of work to reduce the incidence of listeriosis in vulnerable groups (Listeria Risk Management Programme). The need for this specific intervention within the programme resulted from continued outbreaks of listeriosis in healthcare organisations involving ready-to-eat foods. Listeriosis causes the most deaths from foodborne disease, per population (vulnerable groups), in the UK. 73% of listeriosis outbreaks (2003-2012) were associated with sandwiches consumed in hospital. It was found that the causes of most listeriosis outbreaks were down to poor food safety controls and a lack of understanding of controls specific to Listeria in ready-to-eat foods.
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Is guidance required for new or amended legislation?				N
EU?		Domestic?		Insert link

5. Does the guidance go beyond the requirements of the legislation?*	N
<i>If yes, briefly explain/detail</i>	

6. Does the guidance introduce any new requirements on business (including information requests, mandatory forms etc.) not directly required in law?*	N
<i>If yes, briefly explain/detail</i>	

7. Intended audience?	Business	Y	Local Authority (LA)	N
The guidance is specifically aimed at food businesses that operate within the health and social care environments and serve ready-to-eat food to vulnerable groups.				

8. If LA, is guidance intended to change their regulatory approach or otherwise impact on business?*	N
<i>If, yes, explain/detail what and how this will impact on business</i>	

9. If Business, what does the sector look like?
The guidance will be of interest to health care setting that routinely provide ready to eat food for vulnerable people i.e. hospitals and residential care/nursing homes.
To establish the sector size the FSA initially looked to its own local authority enforcement monitoring data on the number of registered food businesses within this sector. However, the FSA food business data category that captures businesses within this sector is too broad and incorporates childminders

and nurseries. We therefore looked to the Care Quality Commission (CQC) data¹⁰, and although this does not distinguish between those services that provide food and those that do not, it was possible to rule out a number of providers types as being extremely unlikely to be involved in this activity i.e. GP surgeries, out of hour, mobile and consulting Drs, primary dentists, independent ambulances, eye clinics, opticians and other walk-in/out-patient style clinics as well as those that operate in domestic settings such as home care providers. The CQC data therefore revealed approximately 25000 care providers that were likely to be within the target audience for the guidance.

Based on the descriptors provided within the CQC data and our own understanding of the sector from the extensive engagement that was carried out in the production of this guidance, it is believe that the sector will involve a wide mix of business size types from micro through to large organisations.

10. What level of employee will be responsible for familiarisation of the guidance?

This would most likely be someone in the position of a catering manager/supervisor.

11. Average wage rate identified?	£15.24ph
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uprated by 20% to account for overheads in line with SCM methodology ¹¹	£18.29ph
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Wage rate obtained from Annual Survey of Hours and Earnings 2016 (Provisional) and based on 'Health Care Practice Manager' which we believe to be the most suitable equivalent position.

12. What is the guidance total word count?	9,375
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13. For revised guidance, what % (approx.) has been changed?	NA
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14. Level of complexity for intended audience	Low
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The guidance is written in plain English and contains non-technical information on the steps necessary to ensure that adequate controls are in place.

15. Any other factors requiring consideration to assess the guidance impact?*

N/A

* If 'Yes' to Questions 6, 8 or 15 please quantify the assessment of the impact

N/A	£0.00
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¹⁰ <http://www.cqc.org.uk/content/how-get-and-re-use-cqc-information-and-data#directory>

¹¹ SCM methodology <http://www.berr.gov.uk/files/file44503.pdf>