Asiantaeth Safonau Bwyd
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Adolygiad o Reolaethau Swyddogol Llaeth Yfed Amrwd
Tudalen grynodeb yr ymgynghoriad

Dyddiad lansio:	**06/02/2019**	**Dyddiad cau:**	**30/04/2019**

Pwy fydd â diddordeb yn yr ymgynghoriad hwn?

Cynhyrchwyr llaeth yfed amrwd/heb ei basteureiddio presennol ac unrhyw gynhyrchwyr llaeth eraill sy'n ystyried cynhyrchu llaeth yfed amrwd yn y dyfodol. Pobl sy'n yfed llaeth amrwd, awdurdodau gorfodi a'r rhai sydd â diddordeb mewn llaeth yfed amrwd.

Beth yw testun yr ymgynghoriad hwn?

Oherwydd cynnydd mewn achosion *(outbreaks)* yn gysylltiedig â llaeth yfed amrwd a chynnydd mewn cynhyrchwyr a gwerthiant llaeth yfed amrwd, cyflwynwyd papur yn amlinellu argymhellion ar gyfer rheolaethau gwell o ran cynhyrchu llaeth yfed amrwd i Fwrdd yr Asiantaeth Safonau Bwyd (ASB) yn eu cyfarfod ym mis Mehefin 2018.
https://www.food.gov.uk/sites/default/files/media/document/Raw%20Drinking%20Milk%20-%20FSA%2018-06-07.pdf
Adolygodd y Bwrdd y dystiolaeth a chytunodd i gefnogi'r argymhellion hyn. Bydd y newidiadau arfaethedig yn ceisio sicrhau mwy o sicrwydd gan gynhyrchwyr bod eu cynnyrch mor ddiogel â phosibl. Bydd y sicrwydd hwn yn berthnasol i'r rheoleiddiwr a'r defnyddwyr. Bydd y newidiadau arfaethedig hefyd yn darparu mwy o gysondeb o'i gymharu â rheolaethau sydd eisoes ar waith yng Ngogledd Iwerddon.

Beth yw diben yr ymgynghoriad hwn?

Rhoi cyfle i bobl sydd â diddordeb roi sylwadau ac adborth ar y newidiadau arfaethedig i gyflwyno rheolaeth swyddogol llaeth yfed amrwd ac effaith gysylltiedig y newidiadau.

Dylid anfon ymatebion i'r ymgynghoriad hwn at:

Cangen Polisi Hylendid Bwyd
Polisi Bwyd
Asiantaeth Safonau Bwyd

Llawr 7
Clive House, 70 Petty France
San Steffan, Llundain
SW1H 9EX

E-bost: foodhygiene.policy@food.gov.uk

A oes Asesiad Effaith ynghlwm?	**Oes X**	**Nac oes**

Adolygiad o Reolaethau Swyddogol Llaeth Yfed Amrwd

Manylion yr ymgynghoriad

ASB – Asiantaeth Safonau Bwyd
RMPA – Cymdeithas Cynhyrchwyr Llaeth Amrwd

Cyflwyniad

Ym mis Mehefin 2018, cyflwynwyd papur penderfyniad i Fwrdd yr ASB i adolygu rheolaethau cyfredol llaeth yfed amrwd. Roedd y papur yn cynnwys argymhellion o welliannau arfaethedig y gellid eu gwneud wrth gyflwyno rheolaethau swyddogol yn ogystal â darparu'r dystiolaeth a ddefnyddiwyd wrth gyrraedd yr argymhellion hyn. Cytunodd y Bwrdd â'r casgliad nad yw'r risg o laeth yfed amrwd mor annerbyniol fel bod modd cyfiawnhau atal oedolion rhag dewis ei yfed, ar yr amod bod rhai rheolaethau'n cal eu bodloni. Fodd bynnag, roedd y bwrdd yn cydnabod bod angen gwelliannau o ran sicrhau rheolaethau mwy cadarn, atebolrwydd a'r angen i weithredwyr busnesau bwyd roi sicrwydd i'w cwsmeriaid a'r rheoleiddiwr bod eu cynnyrch yn ddiogel.

Cynigion

Mae gofynion cyfreithiol wastad wedi bod i weithredwyr busnesau bwyd gofrestru â'r ASB er mwyn cynhyrchu llaeth yfed amrwd, a bod ganddynt system ar waith i nodi, monitro a rheoli peryglon sy'n gysylltiedig â'r cynhyrchiad hwn ac i wirio bod y mesurau rheoli sydd ar waith ar gyfer y peryglon hyn yn effeithiol.
Fel rhan o'r broses o adolygu'r rheolaethau swyddogol, bydd yr ASB fel y rheoleiddiwr yn fwy eglur yn y modd y mae hi'n gofyn i weithredwyr busnesau bwyd ddangos eu bod yn bodloni'r gofynion cyfreithiol hyn. Bydd y rheolaethau newydd yn berthnasol i bob cynhyrchydd newydd a bydd gan gynhyrchwyr sydd eisoes yn bodloni'r gofynion gyfnod o 6 mis i wneud unrhyw newidiadau angenrheidiol.
Bydd cael System Rheoli Diogelwch Bwyd yn ei lle yn caniatáu i gynhyrchwyr nodi pa gamau yn eu systemau cynhyrchu a allai beri risg a sicrhau bod ganddynt fesurau rheoli ar waith i ddileu neu leihau'r risgiau hyn i lefel dderbyniol. Mae dogfennau templed sy'n dangos gofynion sylfaenol y systemau hyn wedi'u cynnwys i gynorthwyo cynhyrchwyr i ddeall yn well sut y gellir sefydlu'r systemau. Gellid defnyddio'r templedi hyn neu un arall sy'n darparu'r wybodaeth gyfatebol.
Mae gan Systemau Rheoli Diogelwch Bwyd dilys gam dilysu sydd wedi'i anelu at brofi a gwirio effeithiolrwydd y mesurau rheoli a gyflwynwyd, gan ganiatáu i gamau unioni gael eu cymryd os oes angen. Ystyrir mai profion cyfnodol yw'r ffordd fwyaf effeithiol o wirio'r systemau hyn, ac o fewn y canllawiau ar gofrestru mae rhestr o'r pathogenau y gellir eu canfod mewn llaeth yfed amrwd. Bydd gofyn i gynhyrchwyr brofi am y pathogenau hyn er mwyn sefydlu a gwirio pa mor effeithiol yw eu system rheoli diogelwch bwyd. Nid yw'r amlder y dylid cynnal profion wedi'i bennu gan y bydd hyn yn amrywio yn dibynnu ar natur y busnes. Yn hytrach, bydd cynhyrchwyr yn penderfynu ar yr amlder sy'n addas gan ddefnyddio eu systemau rheoli diogelwch bwyd a'r risgiau a ddaw i'r amlwg drwy'r system hon er mwyn cyfiawnhau amlderau.

1. Y prif gynnig/gynigion:

- **Mae gan gynhyrchwyr llaeth yfed amrwd System Rheoli Diogelwch Bwyd effeithiol wedi'i wirio ar waith**
- **Dylai mesurau i wirio'r system hon yn effeithiol gynnwys profi am bathogenau a ganfyddir yn aml mewn llaeth yfed amrwd**

2. Effeithiau

Mae asesiad o effaith y newidiadau arfaethedig wedi'i gwblhau ac mae ar gael yn Atodiad 1

3. Y Broses Ymgysylltu ac Ymgynghori

Cynhaliwyd gweithdy ar gyfer cynhyrchwyr ar y cyd ag Undeb Cenedlaethol yr Amaethwyr (NFU) ym mis Mai 2018. Gwahoddwyd pob cynhyrchydd llaeth yfed amrwd i'r gweithdy hwn. Roedd dros 70 o gynhyrchwyr llaeth yfed amrwd yn bresennol yn y digwyddiad hwn, ynghyd â chynrychiolwyr yr ASB, awdurdodau lleol, yr NFU a'r Gymdeithas Cynhyrchwyr Llaeth Amrwd (RMPA). Cafodd gwybodaeth am y newidiadau arfaethedig ei chyfathrebu â phawb a oedd yn bresennol, ac yna cynhaliwyd sesiwn holi ac ateb. Mae ymgysylltiad wedi parhau'n rheolaidd gyda'r RMPA.

Cwestiynau eraill a ofynnir yn yr ymgynghoriad hwn:.

C1: Byddem ni'n croesawu unrhyw safbwyntiau ar y 6 mis sy'n cael ei ganiatáu ar gyfer cynhyrchwyr llaeth yfed amrwd presennol i addasu unrhyw systemau presennol i fodloni'r gofynion arfaethedig.

4. **Dogfennau perthnasol eraill**

Gellir dod o hyd i unrhyw ddogfennau cysylltiedig perthnasol fel Atodiadau isod.

5. **Ymatebion**

Gofynnwn i ymatebion ddod i law erbyn **diwedd y dydd, 30 Ebrill 2019**. Yn eich ymateb, nodwch a ydych yn ymateb fel unigolyn neu ar ran sefydliad neu gwmni (gan gynnwys manylion unrhyw randdeiliaid y mae'ch sefydliad yn eu cynrychioli).

Ar ran yr Asiantaeth Safonau Bwyd, hoffwn ddiolch yn fawr i chi am gymryd rhan yn yr ymgynghoriad cyhoeddus hwn.

Yn gywir,

Colin Thompson
Arweinydd Gweithrediadau Llaeth
Gweithrediadau Maes

Atodiadau

Atodiad A: Gwybodaeth Safonol am yr Ymgynghoriad

Atodiad B: Asesiad Effaith (Saesneg yn unig)

Atodiad C: Rhestr o bawb sydd â diddordeb

Atodiad D: Copi drafft o'r Canllawiau Cofrestru arfaethedig (Saesneg yn unig)

Atodiad A: Gwybodaeth safonol am yr ymgynghoriad

Datgelu'r wybodaeth a ddarperir gennych

Efallai caiff yr wybodaeth a roddir mewn ymateb i'r ymgynghoriad hwn ei chyhoeddi i bartïon eraill neu ei datgelu yn unol â'r cyfundrefnau mynediad at wybodaeth (yn bennaf Deddf Rhyddid Gwybodaeth 2000, Deddf Diogelu Data 2018 a Rheoliadau Gwybodaeth Amgylcheddol 2004).

Os dymunwch i'r wybodaeth yr ydych yn ei rhoi gael ei thrin yn gyfrinachol, byddwch yn ymwybodol bod yna God Ymarfer statudol o dan y Ddeddf Rhyddid Gwybodaeth y mae'n rhaid i awdurdodau cyhoeddus gydymffurfio ag ef. Mae'n ymdrin, ymhlith pethau eraill, â rhwymedigaethau cyfrinachedd.

O ystyried hyn, byddai'n ddefnyddiol pe gallech esbonio i ni pam eich bod yn ystyried yr wybodaeth a roddwyd gennych yn gyfrinachol. Os cawn gais i ddatgelu'r wybodaeth, byddwn ni'n ystyried eich esboniad yn llawn, ond ni allwn roi sicrwydd y gellir cadw cyfrinachedd dan bob amgylchiad.

Ni fydd unrhyw ymwadiad cyfrinachedd awtomatig a gynhyrchir gan eich system TG, ar ei ben ei hun, yn cael ei ystyried fel un sy'n rhwymo.

Yr ASB fydd 'Rheolydd' y data personol a ddarperir i ni.

Pam ein bod ni'n casglu eich data personol?

Mae eich data personol yn cael ei gasglu fel rhan hanfodol o'r broses ymgynghori, fel y gallwn gysylltu â chi ynglŷn â'ch ymateb ac at ddibenion ystadegol. Efallai hefyd y byddwn ni'n ei ddefnyddio i gysylltu â chi am faterion cysylltiedig.

Mae Deddf Diogelu Data 2018 yn datgan y gall yr Asiantaeth Safonau Bwyd, fel adran o'r llywodraeth, brosesu data personol fel bo'r angen er mwyn cyflawni tasg sydd er budd y cyhoedd yn effeithiol h.y. ymgynghoriad.

Beth fyddwn ni'n ei wneud â'r wybodaeth?

Mae'r holl ddata personol rydym ni'n ei brosesu yn byw ar weinyddion o fewn yr Undeb Ewropeaidd. Mae ein gwasanaethau cwmwl wedi'u caffael drwy Gytundebau Fframwaith y Llywodraeth a'u hasesu yn erbyn egwyddorion cwmwl y Ganolfan Seiberddiogelwch Genedlaethol.
Nid oes gan drydydd partïon fynediad at eich data personol oni bai bod y gyfraith yn caniatáu iddynt wneud hynny. Bydd yr ASB weithiau'n rhannu data gydag adrannau eraill y llywodraeth, cyrff cyhoeddus a sefydliadau sy'n cyflawni swyddogaethau cyhoeddus i'w cynorthwyo i gyflawni eu dyletswyddau statudol, neu pan fydd er budd y cyhoedd.

Beth yw eich hawliau?

Mae gennych chi'r hawl i weld yr wybodaeth sydd gennym ni amdanoch chi drwy wneud cais ysgrifenedig i'r cyfeiriad e-bost isod. Os ydych chi ar unrhyw adeg o'r farn bod yr

wybodaeth rydym ni'n ei phrosesu amdanoch chi yn anghywir, gallwch chi wneud cais i'w chywiro. Os hoffech chi wneud cwyn am y ffordd rydym ni wedi trin eich data personol, gallwch chi gysylltu â'n Swyddog Diogelu Data a fydd yn ymchwilio i'r mater.

Os nad ydych chi'n fodlon â'n hymateb neu os ydych chi o'r farn nad ydym yn prosesu eich data personol yn unol â'r gyfraith, fe allwch chi gwyno i Swyddfa'r Comisiynydd Gwybodaeth yn https://ico.org.uk/, neu drwy ffonio 0303 123 1113.

Ein Swyddog Diogelu Data yn yr ASB yw Arweinydd y Tîm Rheoli Gwybodaeth a Diogelwch. Gallwch chi gysylltu drwy anfon e-bost at: informationmanagement@food.gov.uk

Rhagor o wybodaeth

Os ydych chi angen y ddogfen hon mewn fformat sy'n haws i'w ddarllen, anfonwch fanylion at y cyswllt a enwir ar gyfer ymatebion i'r ymgynghoriad hwn a bydd eich cais yn cael ei ystyried.

Mae'r ymgynghoriad hwn wedi'i baratoi yn unol ag egwyddorion ymgynghori Llywodraeth Ei Mawrhydi[1].

[1] www.gov.uk/government/publications/consultation-principles-guidance

Atodiad B. Asesiad Effaith (Saesneg yn unig)

Assessment of Impact
Evidence Base (for summary sheets)
SUMMARY OF NET COSTS

	Annual Costs	**Total (over 10 years)**	**Total NPV**
FSA	-£1,313	-£1,313	-£1,313
FBO	-£267,979	-£2,528,971	-£2,191,941
Total	**-£269,292**	**-£2,545,366**	**-£2,193,254**

Earned Annual Net Direct Cost to Business	£254,649

BACKGROUND
Problem under consideration

1. The Food Standard Agency (FSA) is responsible for ensuring that an effective regulatory regime is in place to verify that Food Business Operators (FBOs) meet their obligation to ensure food is safe and is what it says it is. The FSA is the Central Competent Authority (CCA) responsible for the registration of producers of Raw Drinking Milk (RDM), as well as inspecting RDM sites as part of official hygiene controls, through its Dairy Operations unit.

2. RDM is milk that has not undergone any form of heat treatment (e.g., pasteurisation) that is sufficient to kill harmful bacteria that may be present in the raw milk. Although the consumption of raw drinking milk is not widespread among the general population, there are some consumers who believe that raw milk possesses particular health properties or attributes, in addition to the existing nutritional components. However, the removal of the pasteurisation step does increase the risk for the microbial load contamination obtained during production to be carried through to the finished product.

3. The supply of raw drinking milk is regulated by EU and domestic food hygiene regulations. These regulations place the responsibility for the production and supply of safe food, such as RDM, solely with the FBO. The farmer is the FBO in the case of the supply of the RDM for human consumption. RDM production is subject to additional official controls and requirements on top of standard dairy controls.

4. The FSA is proposing a change which seeks to update the internal measures necessarily adopted by RDM producers during production in order to improve the quality assurance of their product. The current requirements have been in place since 2012; however, they have not kept pace with changes in the production, consumption and distribution of RDM over time, thus requiring modification to adapt to this new environment.

Rationale for intervention

5. An internal audit of RDM controls identified a significant rise in the number of producers and volume of production of RDM across England and Wales. This trend has been matched by an increase in the number of outbreaks of illness associated with the consumption of RDM, especially over the period 2016/17. Intervention is required to reduce unacceptable public health risks, whilst protecting consumer choice.

POLICY OPTIONS

Two options have been identified:

6. **Option 1:** 'Do Nothing', and continue with the current registration/inspection system

7. **Option 2:** Introduction of a Food Safety Management System (FSMS) which will enable FBOs to demonstrate stronger compliance in the production of RDM in England and Wales.

    - To verify that the FBO has adopted the FSMS (which will likely be based on HACCP[2] principles), it has been identified that frequent sampling of produce will be the most applicable method for verification of internal systems. This is the preferred option.

GROUPS AFFECTED

The following groups are affected:

Consumers

8. The requirement to set up and implement a FSMS will ultimately help RDM producers to comply with food hygiene and food standards more effectively. In setting up a robust FSMS RDM producers place themselves in a better position to protect consumers and reduce unacceptable food-related risks. However, should RDM producers pass on the increased cost of production to consumers, the market price of RDM will necessarily rise.

Food Business Operators (FBOs)

9. RDM producers are the primary focus of this proposed policy update. As of 1st January 2019, there are 161 RDM producers in England & Wales[3] that will be affected directly by this proposal. EU and domestic food hygiene regulation stipulates clearly that the responsibility for the production and supply of safe food, such as RDM, lies solely with the producing FBO. As such the proposed policy change will require greater assurance measures to be introduced during the production stage.

The FSA

10. The FSA is the CCA responsible for ensuring that an effective regulatory regime is in place that fully enables and clearly demonstrates to FBOs how to meet their obligation to ensure that the food they produce is safe and is what it says it is.

11. In additional the FSA is responsible for carrying out official hygiene controls of RDM sites via the 41 (as of January 14th 2019) Dairy Hygiene Inspectors (DHIs) the agency directly employs.

Wider Economy

12. By helping RDM producers improve the quality assurance associated with its product, the introduction of a FSMS may lead to a reduction in foodborne illnesses that will help relieve pressure on the National Health Service (NHS), reductions in pain & suffering, as well as forgone economic output due to absence from work. However, as this policy update only affects a very small minority of producers and consumers, these wider effects are likely to be minimal when considered on an aggregate basis.

OPTION APPRAISAL

Option 1: 'Do Nothing', and continue with current registration/inspection system

Costs and Benefits

[2] Hazard Analysis & Critical Control Points.

[3] See Figure 1 in Appendix for map of RDM producers across England and Wales.

13. Option 1 is the baseline on which all other options are appraised. The FSA currently holds no evidence to suggest that any of the important variables in the baseline will change over time in the absence of intervention. In this baseline, it is presumed that RDM producers are not engaged in sampling for pathogens and/or water supply quality, or have a FSMS in place, based on the HACCP principles.[4] With this in mind, the costs and benefits in the baseline across time assume the current number of RDM producers in England and Wales, overall compliance rates, levels of consumer risk and the number of foodborne illness incidents remain constant. Due to the presumptions made, the policy options measured against this status quo represent a worst-case scenario, resulting in an overestimation of the cost.

Options 2: Introduction of a Food Safety Management System which will require FBOs to demonstrate stronger compliance in the production of RDM.

COSTS

14. All estimated and monetised costs used throughout this assessment are in current prices and are measured over a 10-year appraisal period.

Food Business Costs

15. There are 161 RDM producers currently operating across England and Wales.[5] The introduction of the FSMS will necessarily increase the required measures taken by each FBO to guarantee the safety and hygiene compliance of its RDM production. These measures will place an additional cost, both of a transitional and recurring annual nature, on each RDM producer. It must be noted however, that this additional cost will vary per RDM producer in accordance with the agreed measures dictated by their bespoke FSMS.

Familiarisation costs

16. The proposed policy change will initially require RDM producers to familiarise themselves with the new requirements, so they can fully understand what precautionary measures will have to be adopted into their operation. We anticipate this to take a maximum of 2 hours per FBO and will cost on average £31.23 per FBO and £5,027 in total across all RDM producers.[6]

Implementation costs

17. The proposed policy change, namely the introduction of a FSMS system, will require a certain amount of time to construct and subsequently implement. As the FSMS is tailored to the specific operations of each RDM producer the amount of time taken to complete this activity will vary across producers. Additionally, many RDM producers may seek to contract this activity out to external contractors, however we do not account for this option within our calculations. In the absence of data, we have estimated that the average time to complete this activity is 4 hours.[7]

[4] In reality this is unlikely to be the case. The FSA lacks the required data to estimate how many farms already have a FSMS in place.

[5] Taken from published list of RDM producers on FSA website as at 1st January 2019.

[6] Using the Annual Survey of Hours and Earnings (ASHE) 2018 data, the median wage of a manager or proprietor in the agriculture or horticulture sector is £15.61 (including an overhead rate of 30% as suggested in the Green Book). £15.61/hour x 161 RDM producers x 2 hours to familiarise = £5,026 cost to industry.

[7] This average estimation should be viewed as an approximation. As part of the consultation we encourage any contributions by affected businesses which will enable us to build upon our evidence base on this specific issue.

18. The total cost of constructing and implementing a FSMS is estimated to be £62.45 per RDM producer and £10,055 in total for industry.[8]

Sampling costs

19. The most significant cost placed upon FBOs as a result of this policy change will be activities associated with the necessary sampling requirements. At this stage, sampling has been identified as the most appropriate method for which to verify that FBOs are carrying out the necessary internal steps and procedures as dictated by their bespoke FSMS and that these are effective in providing a safe final product. This process involves the following costs and considerations:

    - **Loss in productivity**: in order to extract, package and dispatch the relevant set of samples to a chosen laboratory it is presumed to take 0.5 hours. This is based on the time taken for a DHI inspection to undertake the same task.

    - **Courier services:** once ready to dispatch the FBO will likely have to pay for a courier service to deliver the relevant set of samples to a chosen laboratory.[9] Transporting samples to a chosen laboratory is a cost that producers will likely seek to minimise. This cost will also vary depending on geographical location and chosen courier service provider.[10] Conversations with a key industry stakeholder suggest that the maximum charge of transporting samples is £20 per set of samples.[11] This covers all identified courier options.

    - **Laboratory charges**: using three quotes from accredited laboratories we were able to calculate an average charge per sample of £81.95. This price covers all required pathogen testing, but not water supply quality testing which would have to be included separately (but would also be required on a less frequent basis).

    - **Sampling frequency**: will vary between FBOs that have differing FSMSs and associated risk levels. On average, and in most cases, it is presumed that FBOs will undertake the required pathogen sampling monthly. There may also be scope to reduce sampling frequency if an FBO is able to demonstrate a history of compliance, however this is not accounted for in our estimates.

20. Therefore, the total average estimated annual cost of all identified activities associated with sampling is £1,317 per RDM producer and £212,050 in total for industry.[12]

General Ongoing Costs

[8] Using the ASHE 2018 data, the median wage of a manager or proprietor in the agriculture or horticulture sector is £15.61 (including overheads). £15.61/hour x 161 RDM producers x 4 hours to implement = £10,053 cost to industry.
[9] Many laboratories (such as the National Milk Laboratory) offer in-house courier services.
[10] Other courier options include (but are not limited to) third-party courier services, through the postal service or bypassing courier services altogether and delivering samples independently. These options would require the set of samples to be ice-packed which would incur an additional cost.
[11] This average estimate should be viewed as an approximation. As part of the consultation we encourage any contributions by affected businesses which will enable us to build upon our evidence base on this specific issue.
[12] Annual average laboratory cost of £983.40; Annual courier services costs £240; annual sampling processing productivity loss of £93.68 and; 161 RDM producers across England and Wales. Summating these figures provides us with the total cost estimates.

21. Maintenance and upkeeping of the FSMS will require ongoing record keeping and reporting.[13] These activities are imperative to the ongoing functioning of the FSMS, and record of them will be audited in some form by DHIs as part of official control delivery. As these associated tasks can be incorporated within and alongside other non-related activities, it is difficult to estimate the extra burden of time it will place upon RDM producers. However, in the absence of robust data, we have assumed the average time taken to complete the activities required for record keeping and reporting purposes to take, on average, 0.25 hours per day of milking.[14] If we assume that RDM producer milk their cows five days a week, then the time spent on completing this activity is 1.25 hours a week or 65 hours a year.[15]

22. Therefore, the estimated total annual record keeping and reporting is £254 per RDM producer and £40,848 in total for industry.[16]

Official Controls

23. The burden of official controls to an FBO as a result of this policy change is net zero.[17] Currently RDM producers are subject to four visits a year which, on average, total four hours.[18] Under this policy proposal, the frequency and duration of visits will change, but the productive time lost to official controls will remain constant at four hours per annum.[19]

FSA Costs

Familiarisation costs

24. The proposed FSMS introduction will result in a familiarisation cost to Dairy Health Inspectors (DHIs) who will need to read and familiarise themselves with the changes. FSA enforcement data shows that there are 39 DHIs currently employed on a part-time basis.[20] However, as of January 14th 2019, there will be a team of 9 full-time DHIs, supported by 32 existing part-time DHIs.

25. The FSA estimates that an authorised DHI will invest approximately two hours reading and familiarising themselves with the FSMS requirements expected of FBOs. The familiarisation cost can be monetised by multiplying the total number of hours needed for DHIs to familiarise

[13] Record keeping and reporting will include tasks such as (but not limited to): recording temperatures twice daily and updating training record, on a less frequent basis.
[14] This assumption should be viewed as an approximation. As part of the consultation we encourage any contributions by affected businesses which will enable us to build upon our evidence base on this specific issue.
[15] Based on a 52-week year.
[16] Using the ASHE 2018 data, the median wage of a manager or proprietor in the agriculture or horticulture sector is £15.61 (including overheads). Based on the assumption that a RDM producer is producing RDM 5 times a week across 52 weeks of the year. 65 hours/year x 15.61/hour x 161 RDM producers = £39,579
[17] Whilst the likely effect to the average RDM producer with regards to the change in official controls is likely to be net-zero, inspection time will vary depending on the level of compliance. Furthermore, it is not understood if the policy change will have any significant impact on overall levels of compliance.
[18] Twice to inspect premises and sample produce and twice to sample produce only. Average time taken for an inspection is 1 hour; sampling taking 0.5 hours.
[19] Duration will be increased to an average of 2 hours as DHIs will be required to audit the RDM producer's paperwork associated with their bespoke FSMS and; frequency will be reduced to two visits per year, as the requirement for sampling-specific visits will not be required anymore.
[20] These DHIs are predominantly Meat Health Inspectors (MHIs); however, they have also been trained in dairy and are back-filled in their red meat plants to go out and deliver dairy inspections, on average of one day a week.

themselves with the changes by the average hourly cost of employing those officers. This is estimated at £1,313.[21]

Training costs

26. There are no explicit training costs associated with this policy change. Due to the recruitment of a new team of full-time DHIs (see paragraph 24) there will however be a £30,000 cost to the FSA to deliver enhanced training to these individuals. Whilst this training will deliver guidance on all aspects of dairy, it will also have a focus on current RDM controls. Due to the fact that this training is in response to structural changes in the employment of DHIs rather than legislative changes in RDM production requirements, we have discounted this cost (or apportioned any of it) from our cost estimations.

Official Controls

27. There is a net-zero cost to the FSA with respect to the change in delivery of official controls. As a result of the proposed policy shift, compliant RDM producers can expect less frequent, but longer inspections that amount to the same total annual productive time lost (see paragraph 23). It necessarily follows that the average time spent inspecting sites by DHIs will remain constant. Therefore, there is no change in the costs to deliver official controls.

Total Costs

28. The total costs associated with Policy Option 2 over a 10-year appraisal period are £2,545,366 with a Net Present Value (NPV) of £2,193,254. Industry will assume 99.95% of total costs imposed as a result of this policy. As such, the Earned Annual Net Cost to Business (EANDCB) is £254,649. Benefits were not monetised, therefore the total net cost over the appraisal period is -£2,545,366 with NPV of -£2,193,254.

BENEFITS

Consumers Benefits

Improved Confidence

15. No monetised benefits to consumers have been identified. Despite this, the increased measures required of RDM producers will have a positive impact on RDM consumers: they will have greater assurance over the product they are purchasing.

FBO Benefits

Enhanced Quality Assurance

16. No monetised benefits have been identified to RDM producers. However, the change could possibly impact FBOs positively if they demonstrate greater and sustained compliance which may attract more custom, or indeed attract RDM consumers from other non-complying competitors. However, this effect is likely to be somewhat muted, or entirely, by the necessary increases in production costs to the RDM producer associated with this policy change.

FSA Benefits

Proportional Regulation

17. No monetised benefits have been identified to the FSA. As official controls of RDM production are enforced by the FSA, through its Dairy Operations unit, it is the agencies legislative duty to

[21] Basing an average DHI salary of £25,620 on a 40-hour working week, we calculate the hourly rate as £16.01 (including overheads). £16.01/hour x 41 DHIs x 2 hours to familiarise = £1,313 total cost to FSA.

protect consumers by reducing any risk associated with the production, supply or consumption of RDM. The requirement for RDM producers to adopt a bespoke FSMS, along with appropriate verification activities, will demonstrate that the FSA is a modern, flexible and competent regulator.

WIDER IMPACTS

Small and micro business assessment

18. The UK food industry is comprised of mainly small and micro businesses (generally greater than 90%) and therefore the greatest impact from new measures in the UK will, in most cases, be on small and micro businesses. For this reason, the FSA assesses the impact on small and micro businesses as standard when undertaking impact assessments.

19. Most RDM producers across England and Wales are small or micro businesses. As a result, the FSA does not foresee the policy change to have a significantly disproportionate effect on small or micro businesses.

Unavoidable impact

20. Due to the high density of small and micro businesses in the English and Welsh RDM market, it is unfeasible to exempt said businesses from the proposed policy change as this would fail to achieve the intended effect of reducing unacceptable food-related risks to consumer health. That said, the FSA intends to make every effort to minimise burdens on small or micro businesses through providing clear guidance and general information to RDM producers.

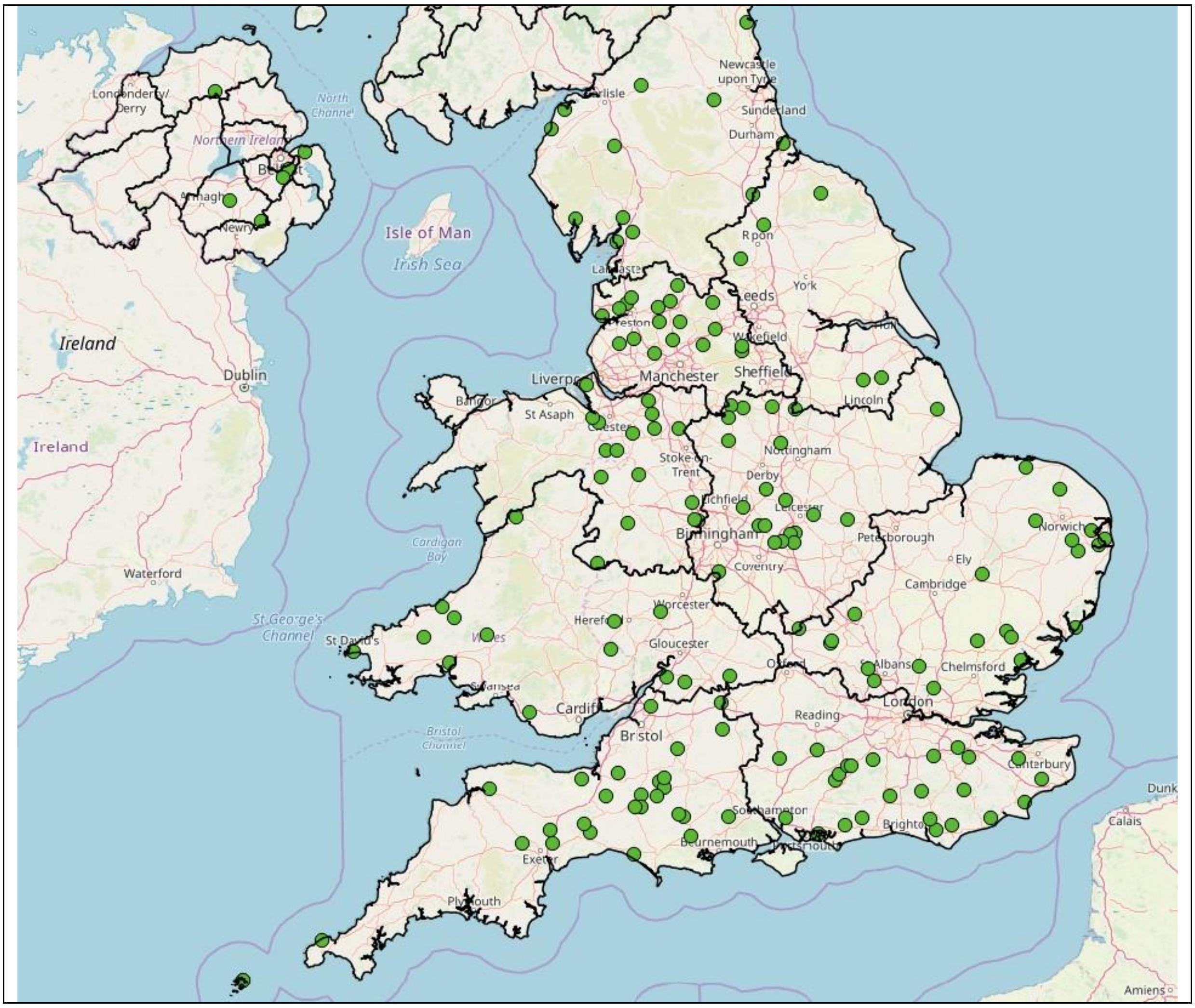
Competition Assessment

Reduction in number of RDM producers

21. The proposed policy change will place an additional burden on RDM producers in the form of increased production costs. If RDM producers are unable to transfer these costs on fully to the consumer, then it may force some producers to drop out of the market. This would lead to a reduction in the number of active RDM producers, which would necessarily reduce competition. As demand for RDM is largely contained locally, any reduction in competition could result in supply imbalances on a per area basis.

Appendix

Figure 1: Spatial mapping of current RDM producers in England, Wales and Northern Ireland



Newcastle upon Tyne
Sunderland
Durham
Carlisle
Londonderry/Derry
North Channel
Armagh
Newry
Isle of Man
Irish Sea
Ireland
Dublin
Ireland
York
Leeds
Preston
Wakefield
Manchester
Sheffield
Bangor
St Asaph
Lincoln
Stoke-on-Trent
Nottingham
Derby
Lichfield
Leicester
Birmingham
Peterborough
Norwich
Ely
Coventry
Cambridge
Cardigan Bay
Waterford
St George's Channel
St David's
Hereford
Worcester
Gloucester
St Albans
Chelmsford
Cardiff
London
Reading
Bristol Channel
Bristol
Canterbury
Southampton
Brighton
Bournemouth
Exeter
Plymouth
Calais
Amiens

Atodiad C. Rhestr o bawb sydd â diddordeb

- A & A M Burrow
- A & C L Gray
- A E & E Garnett Ltd
- A L Betts Ltd
- A M Duguid & Son
- A S & S Morgan
- Aeron Jersey Dairy Products
- Ahimsa Dairy Foundation
- Applebys
- Arla Foods
- Cymdeithas Cynhyrchwyr a Defnyddwyr Llaeth Heb ei Basteureiddio
- Ffermydd Llaeth Sicr
- B & H Griffin
- B & J Hilsdon
- B J & M Tomlinson & Son
- B R Fox
- Baby Milk Action
- Barkers Farm
- Barnowl Jersey Stud
- Beaconhill Farm
- Blackburn & Haynes
- Bonsalls Mercaston
- Boydells Dairy Farm
- Brian Haigh
- Bridgend Creamery – Dairy Farmers of Britain
- Bwrdd Caws Prydain
- Cymdeithas Defaid Llaeth Prydain
- Brookes Wye Valley Dairy Co Ltd
- Buffalo Dairy Limited
- C L Bowles-Jones
- C L G Wadman & J Wadman & Sons
- C W F Hughes & Son
- Camphill Village Trust
- Carpenters Hill Farm
- Charles Wray
- Christine Page
- Chuckling Goat Ranch
- Clandeboye Estate Co Ltd
- Combe Hay Mare's Milk

- Coston Hall Farms Ltd
- Cothi Valley Goats
- Culmore Organic Farm
- Cwmheidir Farm Dairy
- Cymdeithas Frenhinol Ffermwyr Llaeth Prydain
- D & C Gibson
- D & P Thompson
- D & S A Boden
- D A & J L Bennion
- D A Howie & Sons
- D G & J R Browne
- D J, M J P W House
- D K & M J & N Parris
- D P & S J Berry
- D S & E J LE May
- Cyngor Llaeth
- Cyngor Llaeth Gogledd Iwerddon
- Dairy Crest
- Dairy Crest Group Plc
- Dairy Development Centre
- Dairy Produce Packers Ltd
- Dairy UK Ltd
- Dairy UK Northern Ireland
- Dairy UK Scotland
- DairyCo
- Dansco Dairy Products Ltd
- Dee Dairy Services
- Delph House Farm
- Diana M Morgan and Thomas J Dunning
- Dreamers Farm
- Drew
- Dyfi Dairy
- E & D E Horn
- E A Mayhew & Sons Limited
- E H Arden & Son
- E S Burroughs & Sons
- E T Tomlinson & Son
- E W Gill and Sons Limited
- Edgar & Son
- Ellie's Dairy
- Emma Aldous
- Emma's Dairy
- European Dairy Association

- F S Sturrock & Sons
- F W Read & Sons Ltd
- Fen Farm Dairy Ltd
- First Milk Limited
- G & A Adderson
- G D & M Rodgers & Sons
- G M & H J Fern
- G Neagle
- Gilcombe Farm
- Goat Dairy Trade Association
- Goat's Milk Processors Federation
- Goat's Milk Processors Federation
- Golden Acre Dairy Foods Ltd
- Golden Valley Goats Ltd
- Greys Milking Sheep Co
- H G Robinson & Sons Limited
- H G Witt And Son
- H S Bourne
- H W Oultram & Co
- Halton Farms Ltd
- Hanna
- Heard Cattle Company
- Heath Farm Partnership
- Hinton Farm Ltd
- Hollypark Organics
- Hopewell Farm Foods
- Hugh Dibble
- J & B Richards
- J & M & E A Taylor
- J & S Y Kenyon & Sons
- J A Haigh & Sons
- J D Hetherington & Sons
- J H & P J Turner
- J R & S E Cook
- Janvil Dairy Goats
- Jenkins Ty Hen Limited
- Jennifer M Daw & Barry A Daw
- Joanne M Power
- John S Pile (Farms) Ltd
- Jon Appleby & Joy Appleby
- L V & D F Dakin & Partners
- Leicestershire Handmade Cheese Co
- Little Acres Goat Products

- Little Arthur Green Farm
- Llaeth y Llan Village Dairy
- Llanfaes Dairy
- Londwood Farm
- Long Clawson Dairy Limited
- Loseley Dairy Ice Cream Limited
- M & M Tattersall
- M E & M E Davenport
- M P Mason
- M R & K M Pring
- M T Partington
- M/S D W & C M Evans
- M/S J J & M A Park & Son
- Mario's Luxury Dairy Ice Cream Fecci's Ice Cream Ltd
- Mark Stevens
- Mays Farm Ringmer
- McDowell
- Meggy Moo's Limited
- Messrs Hughes
- Messrs M L & J M Richardson & Sons
- Messrs Walsh
- Michael J King, Gemma M King, Richard J King and Kathleen A King
- Milk Link Limited
- Milk Link Limited (Lockerbie Creamery)
- Monarch Farms
- Mr & Mrs W Wales
- Mr A W & Mrs J King
- Mr William A E Fox
- Muller Dairy (UK) Limited
- N & J McLintock
- N Shaw & Sons
- National Cattle Association (Dairy)
- National Farmers Union
- National Farmers Union Cymru
- National Sheep Association
- Norsworthy Dairy Goats
- Oak Tree Cottage
- Old Plaw Hatch Farm Limited
- Olive Farm (Babcary) Ltd
- P & C Attfield
- P & R E Kimber
- P G T Hook & Son
- P J Ikin

- P Kerley Contractor Ltd
- P L & K J Boam
- Pemberton's Dairies
- Peter Hill & Son
- Plainspot Farm
- Plas Farm Denbigh Farmhouse Dairy Ice Cream and Yogurt
- Provision Trade Federation
- Pulford Farm Dairies
- Quality Milk Producers Ltd
- R & J Morton
- R & K F Dumelow
- R C Dilks
- R C Hollinshead
- R E Snowdon & Son
- R H Trivett & Son
- R J Gorst
- R J, B C & N W J Monies
- R P Granville & K J Granville
- R S T & S A Morgan
- Rachel's Dairy Limited
- RAWMI
- Red Tractor Assurance Dairy (formerly ADF)
- RMPA
- Robert Wiseman Dairies PLC
- S E Alderman
- S E M & W L Thomas
- S G Lee & Sons
- Specialist Cheesemakers Association
- Stephen Furnival
- Stilton Cheesemakers Association
- Stowford Manor Farm
- Strathroy Dairy Ltd
- Stroud Micro Dairy Limited
- Susan Root
- Sustain: The Alliance for Better Food and Farming
- T & S Farms
- T C Alderson & Son
- T D Prince
- T E Lander
- T M Garry
- T M Woodcock and Partners
- T Smith & Sons Ltd
- Tenant Farmers Association

- The Calf at Foot Dairy
- The Goodwood Estate Company Ltd
- The Welbeck Estate Co Ltd
- Thomas Parkinson
- Top Paddock Farming Partnership
- Trethowan's Dairy Ltd
- Trude Farm
- Undeb Amaethwyr Cymru
- Undeb Bwyd a Ffermio Menywod
- United Dairy Farmers Ltd
- United Dairy Farmers Ltd (Dale Farm Ltd)
- W Dale & Sons
- W F Farms
- W S Burrow & Son
- Weir's Organic Farm
- West Country Water Buffalo Limited
- Wildcroft Rare Breeds

Atodiad D. Canllawiau Cofrestru Drafft arfaethedig ar gyfer Cynhyrchwyr Llaeth Yfed Amrwd yng Nghymru a Lloegr (Saesneg yn unig)

Registration guidance document for raw drinking milk producers in England and Wales

Publication Date: 23/01/2019

Last Reviewed:

Revision history

Revised	Purpose of revision and paragraph number	Revised by
23/01/2019	Original document production	C Thompson

Summary

Intended audience:	• Manufacturers and processors
Which UK nations does this cover?	England and Wales
Purpose:	This document is intended to provide guidance on both legal requirements and expectations on the processes and systems needed to gain registration to supply Raw Drinking Milk direct for human consumption
Legal status:	This document provides advice on policy expectations as well as regulatory guidance on legal requirements
Key words	• Dairy products • Food law, monitoring and controls • Hygiene and food safety • Labelling, composition and lot marking of food • Nutrition and health claims
Review date	01/02/2020

Contents

Introduction

1. In recent years, there has been a growing demand for the consumption of raw unpasteurised milk that has not undergone any form of heat treatment sufficient to kill harmful bacteria that may be present in the raw product.

2. Although consumption of raw drinking milk is not widespread some consumers believe it possesses particular health properties in addition to its standard natural components. There are currently no scientifically proven health benefits linked to the consumption of raw milk in England and Wales, therefore claiming or advertising such benefits could prove mis-leading.

3. The lack of pasteurisation increases the risk of pathogens obtained during production being carried through to the product sold to the final consumer. It is for this reason that raw drinking milk as a ready-to-eat product must clearly carry the health warning "*This milk has not been heat-treated and may therefore contain organisms harmful to health"*

4. The Food Standards Agency (FSA) therefore advises that consumers who have a weakened immune system and are particularly vulnerable to food poisoning should not consume unpasteurised milk, cream or products made from raw milk which have not gone through a thermal process to kill bacteria (e.g. pasteurisation). Vulnerable groups include children, pregnant women, older people and those who are unwell, have chronic illness and/or are immunocompromised.

5. Sales of raw drinking milk direct for human consumption are restricted in England and Wales. Further details around these sales restrictions can be found at:

   https://www.food.gov.uk/business-guidance/raw-drinking-milk-hygiene-guidance

   There is also information included at Annex B.

6. FSA Dairy Operations carry out official controls (hygiene inspections and sampling) at dairy production holdings supplying raw drinking milk direct to the final consumer.

Intended audience

7. This guidance is intended to assist current producers and anyone who is considering becoming a producer of “Raw Drinking Milk” (RDM) intended for supply direct to the consumer.

Purpose of guidance

8. This document is intended for food business operators (FBO’s) planning to supply raw drinking milk direct for human consumption. Some provisions for raw drinking milk produced from species other than cows are subject to alternative controls, further details of which can be found later in this document. The purpose of the guidance is to assist RDM producers in understanding the specific food hygiene requirements relating to the registration, production and sale of raw drinking milk in England and Wales. This document has been produced to provide an overview of the requirements of the legislation and FSA policy on the subject and should be read in conjunction with the legislation itself. The guidance should not be taken as an authoritative statement of interpretation of the law, as only the courts have this power. References to legislation in this guidance mean the legislation in its amended form.

Legal status of guidance

9. This guidance note has been produced to provide advice on the legal requirements of:

- *Regulation (EC) No. 178/2002 General Food Safety Law*
- *Regulation (EC) No. 882/2004 General Rules for Official Controls*
- *Regulation (EC) No. 852/2004 General Rules on Hygiene*
- *Regulation (EC) No. 853/2004 Hygiene Rules for Food of Animal Origin*
- *The Food Safety & Hygiene (England) Regulations 2013*
- *The Food Hygiene (Wales) Regulations 2006*
- *Regulation (EC) No. 2073/2005 Microbiological Criteria of Foodstuffs*

10. Businesses with specific queries may wish to seek the advice of their local Dairy Hygiene Inspector. For queries on approval and the further

processing of dairy products, businesses should contact the trading standards / environmental health department of the local authority of the area where their business is located.

11. The guidance notes on legal requirements cannot cover every situation and you may need to consider the relevant legislation itself to see how it applies in your circumstances. If you do follow the guidance notes they will help you to comply with the law.

Registration

12. All farms producing raw drinking milk must notify and register with the FSA's Registrations and Approvals team [contact details below] and request a registration package, prior to the production and sale of raw drinking milk. This document explains the procedure you would need to follow to gain such registration before you can legally produce and sell RDM.

13. Food Standards Agency (Approvals & Registrations Team)
Kings Pool
Peasholme Green
York
YO1 7PR
Tel; 01904 232060
Email, approvals@food.gov.uk

Requirements for Raw Drinking Milk

14. As the Central Competent Authority responsible for registration of RDM producers, the following section sets out the standards that the FSA will expect producers to comply with in order to be registered for RDM production and sale.

15. To comply with all of the relevant safety and hygiene regulations, farmers supplying raw drinking milk direct for human consumption should ensure that their milk meets the criteria contained within.

16. Schedule 6 of The Food Safety and Hygiene Regulations (England) 2013 and The Food Hygiene (Wales) Regulations 2006, which specify that raw milk must meet the following standards

    a. Plate count at 30°C (cfu per ml) ≤ 20,000

    b. Coliforms (cfu per ml) < 100

17. Producers are responsible for establishing the appropriate date of minimum durability, which in the case of a ready to eat perishable product such as RDM would be the “use-by” date. This durability mark must provide assurance through a validated scientific method, such as historical test date if available or through conducting shelf life studies that the milk continues to meet the microbiological standards above, as well as those contained within the EU microbiological criteria regulations (Regulation (EC) 2073/2005 – see below).

18. The product must continue to meet the legislative criteria and retain acceptable organoleptic (taste, texture, smell, appearance), microbiological and chemical characteristics. Advice on shelf-life studies is available from reputable microbiological testing laboratories. Regulation (EU) 1169/2011 sets out the provisions for food information to consumers and defines the “date of minimum durability” of a food as the date until which the food retains its specific properties when properly stored.

19. Article 24 of Regulation (EU) 1169/2011 sets out the minimum durability requirements for food and requires that in the case of foods which, from a microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the ‘use by’ date. After the ‘use by’ date a food shall be deemed to be unsafe in accordance with Article 14(2) to (5) of Regulation (EC) No 178/2002.

20. Regulation (EC) No. 2073/2005 Microbiological Criteria of Foodstuffs establishes food safety criteria for various pathogens and provides limits for *Listeria monocytogenes* in ready to eat food such as RDM (Annex I, Chapter 1, point 1.2 applies). Producers must ensure that RDM complies with the appropriate criterion throughout the shelf-life of the product and are obliged to withdraw product batches from the market if this criterion is not met (Article 19 of Regulation (EC) 178/2002). Producers can demonstrate compliance by carrying out testing against the appropriate criterion when validating or verifying that their food safety management system is functioning correctly. Producers should therefore decide the appropriate testing frequency in the context of their food safety management system. It is recommended that the frequency of this testing matches that of other tests being undertaken by the producer.

21. Where RDM has a shelf-life of less than 5 days (up to 4 days) it may be assumed that *Listeria Monocytogenes* will not grow and Annex I, Chapter 1, point 1.3 applies. In this case producers should demonstrate compliance with the limit of 100 colony forming units (cfu) per ml.

22. In order to allocate a longer shelf-life, producers need to demonstrate that *Listeria Monocytogenes* will not exceed 100 cfu per ml throughout the shelf life of the product and criterion 1.2a applies. This may be demonstrated by historical test data, if available, or by carrying out shelf life studies.

23. If producers cannot satisfy the FSA that the level of *Listeria monocytogenes* will remain below 100 cfu per ml throughout the desired shelf life, the product shelf-life should be limited to 4 days or criterion 1.2 b applies. This requires the producer to demonstrate *Listeria monocytogenes* is absent at the end of production (e.g. bottling).

24. Other standards for raw drinking milk include:

Microbiological safety

25. Regulation (EC) No 178/2002, Article 14 requires that food is not placed on the market if it is unsafe, and therefore, milk should not contain harmful bacteria. Sampling has found that the following harmful bacteria / pathogens are also associated with and may be present in raw milk:

a. Salmonella spp 0 cfu/25ml

b. Campylobacter spp 0 cfu/25ml

c. Shiga Toxin E.Coli 0 cfu/25ml

d. Coagulase positive staphylococci 20cfu/ml

Somatic Cell Count (SCC) and Plate Count (at 30C)

26. All milk produced and sold must meet the requirements for somatic cell count and plate count as outlined in Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, Part III, point 3 which requires that:

Raw cows milk:

a. SCC: The rolling geometric average must be equal or below 400,000 per ml (over a three-month period, with at least one sample per month)

b. Plate Count: The rolling geometric average must be equal or below 100,000 per ml (over a two-month period, with at least 2 samples per month)

Raw milk from other species:

c. SCC: There is no legal requirement to sample for SCC

d. Plate Count: The legislation splits the requirement into 2 different criteria depending on the intended use:

   i. Milk intending to produce heat treated products: The rolling geometric average must be equal or below 1,500,000 per ml (over a two-month period with at least 2 samples per month)

   ii. Milk intended to produce non-heat-treated products: The rolling geometric average must be equal or below 500,000 per ml (over a two-month period, with at least 2 samples per month)

Antibiotics.

27. FBO's must have procedures in place to ensure that their raw drinking milk is not placed on the market if it contains antibiotic residues above the legal limit. Regulation (EC) No 37/2010 sets out the Maximum Residue Limits (MRL's) for individual veterinary medicines in foodstuffs of animal origin.

Tuberculosis (TB) / Brucellosis (BR) status:

28. Raw milk direct for human consumption must come from a herd that his officially TB free and either BR free or officially BR free.

Water supply requirements.

29. All water used in the parlour, milk storage room and milk filling areas must be potable or clean and the following microbiological standards for water are expected:

a. Colony count @ 22C No abnormal change (guideline <100/ml)

b. Colony count @ 37C No abnormal change (guideline <10/ml)

c. Coliforms 0/100ml

d. Escherichia coli 0/100ml

e. Enterococci 0/100ml

f. Clostridium perfringens 0/100ml

30. Potable or clean water must not contain any harmful bacteria (pathogens) and results of water samples for harmful bacteria must demonstrate that there are “none present in 100ml” for the water supply to be considered acceptable for use.

Requirements for testing

31. FBOs supplying raw drinking milk direct for human consumption will need to consider how they will demonstrate that the hygienic controls they have in place via their food safety management systems (FSMS) are effective and how they can prove that their product meets the requirements mentioned above. The FSA considers that the best way to verify these systems is by undertaking microbiological testing.

32. FBO’s will be expected to provide one full set of test results (plate count, coliforms and pathogens) for the milk and the water supply which demonstrate the above requirements have been met for each month during 2

consecutive months before raw milk supply is allowed to commence. Thereafter the frequency of testing is as outlined below:

33. Frequency of testing will differ depending on the nature and style of the business it is applicable to. FBO's will be required to refer to the FSMS and the assessment of the risks associated to their production systems to justify the frequency at which they decide to test their product. The points below are our policy guidelines for testing.

a. **Raw milk**: Plate Count and Coliform

b. **Raw milk**: Pathogens (Salmonella spp, Campylobacter spp, STEC)

c. ***Listeria Monocytogenes***: Requirements for testing are covered in the shelf life section earlier in this document

34. In addition to this FBO's will be asked to provide assurance that the water that they use is safe, the only way to do this is by testing the water. The frequency of the verification testing of the water should again be based on risk.

35. If testing identifies the presence of harmful bacteria (pathogens) in the milk or water, **sales of raw drinking milk must cease immediately**. The root cause of the problem must be identified and corrective action taken to prevent its reoccurrence. Further testing should be undertaken to verify that the corrective action taken has been effective and the FSA must be kept informed. Supply must not resume until at least 2 consecutive satisfactory results taken from different batches of milk are obtained with the final sample being a verification sample taken by the FSA.

36. If plate count and/or coliform testing indicates levels greater that the legal requirements, we recommend that sales cease. The FBO should take steps to investigate the cause of the problem and take corrective action to prevent reoccurrence. Further sampling should be undertaken to verify if the corrective action taken has been effective. Should this testing show results that continue to fall short of the legal standards required, sales of raw milk should cease, further detailed investigation should take place and a continued cessation of sales should continue until satisfactory results are achieved.

37. **Please note:** Additional somatic cell count, plate count and antibiotic testing is not required if the majority of milk is still purchased and tested by milk purchaser. The milk purchaser will carry out this testing and report results to the FBO and the FSA. Any results indicating the presence of antibiotic residues and/or high somatic cell counts/plate counts should be reported to the FSA by the milk purchaser. If FBO's are only selling RDM and do not sell to a milk purchaser, they will need to consider how they are going to demonstrate compliance with the criteria and undertake such testing themselves.

Reporting results to FSA and verification testing by FSA.

38. All results that do not meet the required standards must be reported to the FSA as soon as these results are available. FSA Dairy Hygiene Inspectors (DHI) will check all test results during inspections. In addition to the FBO's own testing programme, the FSA has a legal obligation to undertake verification sampling. DHIs will carry out verification sampling and testing of RCDM to verify compliance with microbiological standards. A fee of £63 will be charged by the FSA to the FBO for each sample collected. Routinely this sampling will take place twice per year, however the FSA reserves the right to increase this sampling frequency should there be any evidence to demonstrate that this is necessary. Alternatively, the sampling frequency may be decreased should there be evidence to demonstrate that this is possible (i.e. the producer is able to provide evidence of historic compliance with the micro criteria demonstrating that FBOs own systems and verification sampling are effective. This will require a minimum of 6 consecutive months of satisfactory results). The minimum frequency of testing will be once per year.

39. **Note; Sampling from species other than cows will be undertaken by Local Authority (LA) officers**.

40.

Labelling of Raw Drinking Milk

41. Raw milk must be labelled 'Raw milk' (as required by Regulation (EC) No 853/2004). Schedule 6 of The Food Safety and Hygiene (England|) Regulations 2013 or The Food Hygiene (Wales) Regulations 2006 requires that a health warning must be provided to inform consumers that the milk has

not been pasteurised and may contain organisms harmful to health. This is applicable to RDM produced from all species with the exception of buffalo and is as follows:

a. England:

42. CONTAINER: *"This milk has not been heat-treated and may therefore contain organisms harmful to health."* and/or

43. NOT PREPACKED: *"Milk supplied in this establishment has not been heat-treated and may therefore contain organisms harmful to health."*

a. Wales:

44. CONTAINER: *"This milk has not been heat-treated and may therefore contain organisms harmful to health."* and/or

45. NOT PREPACKED: *"Milk supplied in this establishment has not been heat-treated and may therefore contain organisms harmful to health."* And

46. *"The Food Standards Agency strongly advises that is should not be consumed by children, pregnant women, older people or those who are unwell or have chronic illness."*

47. For milk which is sold in a pre-packed container, the health warning must appear on a label attached to the container in which that milk is sold. In the case of any raw milk which is not prepacked and is sold at a farm catering operation, e.g. a farm shop or B&B, the health warning must appear on a ticket or notice that is readily discernible by an intending purchaser at the place where the purchaser chooses that milk. Where vending machines are used, the health warning must be clearly displayed to the purchaser at the point of purchase.

48. Other aspects of food labelling are the jurisdiction of the Local Authority and any advice required on to ensure compliance with other food standards, labelling and weights and measures requirements should be directed to the Environmental Health / Trading Standards departments at your Local Authority. As stated in paragraph 17, RDM is a perishable product and Regulation (EU) 1169/2011, Article 24 requires that a "use-by" date determined through shelf life testing is applied to the labels / product. There is an exception for reusable bottles (i.e. the bottle does not need to bear the

durability marking), but information on durability would still need to be provided by the producer to the consumer via alternatives means. The shelf life of the product would need to be defined. The FBO must have an appropriate labelling system in place that complies with all legal requirements.

Food Safety Management Systems (FSMS)

49. Regulation (EC) No. 178/2002 General Food Law places the responsibility for the production and supply of safe food, such as raw drinking milk, solely with the FBO. As the supplier of the raw drinking milk direct for human consumption, the FBO has the responsibility for ensuring that their milk does not present a health risk to consumers and they must demonstrate to the competent authority what measures have been taken to ensure they have in place a FSMS which is designed to identify and control all relevant hazards associated with the production of raw drinking milk.

50. Having a documented FSMS will help FBO's to demonstrate how they comply with food safety and hygiene legislation and control food safety hazards. FBO's should consider the following 7 steps when designing their food safety management plan:

a. Conduct a hazard analysis. (Identify what could go wrong i.e. the hazards)

b. Identify where controls should be in place

c. Set critical limits at each control. (Decide the parameters that will dictate acceptability against unacceptability)

d. Establish a monitoring system for each. (Carry out checks to determine that the control is working)

e. Establish corrective action. (Decide what to do when it goes out of control – how to put it right and prevent it occurring again)

f. Establish verification procedures to determine if the system is working effectively. (Prove that the FSMS is working)

g. Establish documentation and record keeping.

51. Examples of documentation that can be used as part of your FSMS can be found at Annex A. This is not an exhaustive list and the dairy hygiene inspector may discuss other options with you at the time of inspection.

Withdraw/recall procedures.

52. FBOs will be required to have a documented procedure to withdraw and/or recall product which is deemed unsafe for human consumption, as required by Article 19 of Regulation (EC) 178/2002. This documented procedure would depend on how this product is marketed (e.g. internet sales, distributor, social media advertising, website etc).

Registration inspection of dairy production holdings.

53. The DHI will carry out a registration visit once the documentation provided by the FBO (as above) has been deemed satisfactory. The aim of this visit is to assess the following:

a. Implementation of the FSMS, cleaning protocols, shelf life determination, veterinary drug control system, identification of cows not being milked for human consumption, etc;

b. Assessment of the labelling of RDM and proposed sales routes;

c. General farm hygiene conditions, hygiene facilities, type of parlour/milking, milking operations, animal cleanliness, etc; and

d. General management of the farm, confidence in management, etc.

54. **Please note:** bottling operations are currently under LA's official controls and the local EHO would need to be contacted to arrange a visit to assess the bottling/filling operation.

Publication of compliance category.

55. Registration details of all Raw Drinking Milk establishments together with their compliance rating following the most recent dairy hygiene inspection are published on the FSA website, see link below:

https://www.food.gov.uk/business-industry/farmingfood/dairy-guidance/rawmilkcream

References

 Regulation (EC) No. 178/2002 General Food Law

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02002R0178-20140630&qid=1478866165051&from=EN

 Regulation (EC) No. 882/2004 General Rules for Official Controls

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R0882 20140630&qid=1478866265644&from=EN
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0882&qid=1539678432266&from=EN

 Regulation (EC) No. 852/2004 General Rules on Hygiene - *sets out the general hygiene rules to be applied by all food businesses to protect customers.*

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R0852-20090420&qid=1478867055283&from=EN

 Regulation (EC) No. 853/2004 Hygiene Rules for Food of Animal Origin - *lays down specific hygiene rules for food of animal origin including milk.*

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R0853-20160401&qid=1478867135454&from=EN

 The Food Safety and Hygiene Regulations (England) 2013 or The Food Hygiene Regulations (Wales) 2006 – *these regulations make provision for the execution and enforcement of EU food hygiene regulations in England and Wales and places restrictions on the sale of raw drinking milk intended for direct human consumption.*
http://www.legislation.gov.uk/uksi/2013/2996/contents/made

http://www.legislation.gov.uk/wsi/2006/31/contents/made

 Regulation (EC) No. 2073/2005 Microbiological Criteria of Foodstuffs

56. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02005R2073-20140601&qid=1439307127534&from=EN

Review

57. The FSA aims to keep all guidance material up to date and undertakes regular reviews of this material to ensure it is still relevant. The

next scheduled review date for this guidance is intended to be on or around 04/02/2020 or sooner if deemed necessary.

58. The FSA welcomes user feedback on guidance, including reports of any broken links to reference material or other content that may require updating. Please use the contact details below.

Contacts

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Annex A: Model documentation

59. Annex A gives examples of the types of documented checks that should be considered for use in the FSMS, this list is not exhaustive and other options can be suggested by the DHI as part of their inspections.

Vetinary Records

You can use this sheet to write down and record the use of veterinary medicines within your herd; it is important that these records are kept up to date and are accurate. Entries should be made within 72 hours of treatment

60. Name of veterinary medicine	61. First date of use	62. Identity of animal/group treated	63. Person administering medicine	64. Date treatment finished	65. Withdrawal period end date*			66. Total quantity of medicine used	67. Batch No.	68. Source of medicine
					69. Milk	70. Meat	71. Other			
72. Example	73. 01/5/12	74. 100056	75. A. Herdsman	76. 08/5/12	77. 15/5/12	78. 20/5/12	79.	80. 15 ml	81. 0001	82. Vet
83.	84.	85.	86.	87.	88.	89.	90.	91.	92.	93.
94.	95.	96.	97.	98.	99.	100.	101.	102.	103.	104.

105.	106.	107.	108.	109.	110.	111.	112.	113.	114.	115.
116.	117.	118.	119.	120.	121.	122.	123.	124.	125.	126.
127.	128.	129.	130.	131.	132.	133.	134.	135.	136.	137.
138.	139.	140.	141.	142.	143.	144.	145.	146.	147.	148.
149.	150.	151.	152.	153.	154.	155.	156.	157.	158.	159.
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215.	216.	217.	218.	219.	220.	221.	222.	223.	224.	225.

Veterinary Records

Disease controls

226. Animal ID	227. Date	228. Type of infection	229. Treatment (if applicable) See medicine records	230. 231. Animal isolated?			232. Follow up notes
				233. Yes	234. No	235. Date	
236. Example 0012	237. 02/3/12	238. TB positive	239. n/a	240. X	241.	242. 01/3/12	243. Removed from herd 08/3/12
244.	245.	246.	247.	248.	249.	250.	251.
252.	253.	254.	255.	256.	257.	258.	259.
260.	261.	262.	263.	264.	265.	266.	267.
268.	269.	270.	271.	272.	273.	274.	275.
276.	277.	278.	279.	280.	281.	282.	283.
284.	285.	286.	287.	288.	289.	290.	291.
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380.	381.	382.	383.	384.	385.	386.	387.
388.	389.	390.	391.	392.	393.	394.	395.
396.	397.	398.	399.	400.	401.	402.	403.

Cleaning Records

404. Date	405. Area	406. Chemicals used?	407. Water Temperature	408. 409. Cleaning Details			410. Notes
				411. Time	412. Initials	413. Complete?	
414. 01/01/2019	415. Bulk Tank	416. Provide example	417. Provide record	418. 0830	419. JB	420. Y	421. Visual check undertaken once cleaning completed
422.	423.	424.	425.	426.	427.	428.	429.
430.	431.	432.	433.	434.	435.	436.	437.
438.	439.	440.	441.	442.	443.	444.	445.
446.	447.	448.	449.	450.	451.	452.	453.
454.	455.	456.	457.	458.	459.	460.	461.
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470.	471.	472.	473.	474.	475.	476.	477.
478.	479.	480.	481.	482.	483.	484.	485.
486.	487.	488.	489.	490.	491.	492.	493.
494.	495.	496.	497.	498.	499.	500.	501.
502.	503.	504.	505.	506.	507.	508.	509.

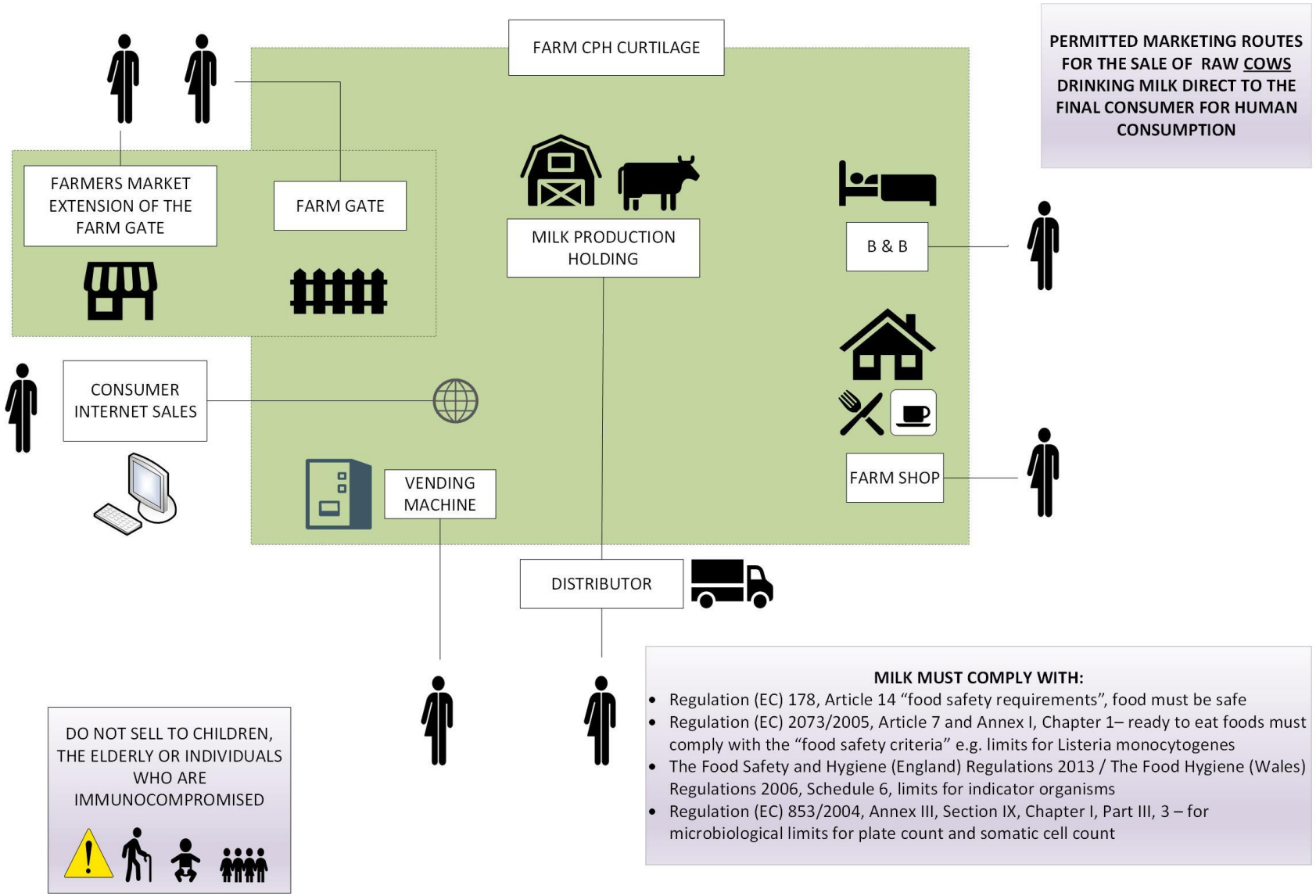
510.	511.	512.	513.	514.	515.	516.	517.
518.	519.	520.	521.	522.	523.	524.	525.
526.	527.	528.	529.	530.	531.	532.	533.
534.	535.	536.	537.	538.	539.	540.	541.
542.	543.	544.	545.	546.	547.	548.	549.
550.	551.	552.	553.	554.	555.	556.	557.
558.	559.	560.	561.	562.	563.	564.	565.
566.	567.	568.	569.	570.	571.	572.	573.
574.	575.	576.	577.	578.	579.	580.	581.

Temperature Check Records

582. Date	583. Time	584. Product	585. Temperature	586. 587. Method of Recording			588. Notes
				589. Manual Probe	590. Auto Reading	591. Initials	
592. 01/01/2019	593. 0830	594. Bulk Tank	595. 3.4C	596.	597. X	598. JB	599. Temperature taken from digital output on tank.
600. 01/01/2019	**601.** 1115	**602.** Final Product Container	**603.** 2.9C	**604.** X	**605.**	**606.** JB	**607.** Calibrated probe used to test milk in customer fridge
608.	**609.**	**610.**	**611.**	**612.**	**613.**	**614.**	**615.**
616.	**617.**	**618.**	**619.**	**620.**	**621.**	**622.**	**623.**
624.	**625.**	**626.**	**627.**	**628.**	**629.**	**630.**	**631.**
632.	**633.**	**634.**	**635.**	**636.**	**637.**	**638.**	**639.**
640.	**641.**	**642.**	**643.**	**644.**	**645.**	**646.**	**647.**
648.	**649.**	**650.**	**651.**	**652.**	**653.**	**654.**	**655.**
656.	**657.**	**658.**	**659.**	**660.**	**661.**	**662.**	**663.**

664.	**665.**	**666.**	**667.**	**668.**	**669.**	**670.**	**671.**
672.	**673.**	**674.**	**675.**	**676.**	**677.**	**678.**	**679.**
680.	**681.**	**682.**	**683.**	**684.**	**685.**	**686.**	**687.**
688.	**689.**	**690.**	**691.**	**692.**	**693.**	**694.**	**695.**
696.	**697.**	**698.**	**699.**	**700.**	**701.**	**702.**	**703.**
704.	**705.**	**706.**	**707.**	**708.**	**709.**	**710.**	**711.**
712.	**713.**	**714.**	**715.**	**716.**	**717.**	**718.**	**719.**
720.	**721.**	**722.**	**723.**	**724.**	**725.**	**726.**	**727.**
728.	**729.**	**730.**	**731.**	**732.**	**733.**	**734.**	**735.**
736.	**737.**	**738.**	**739.**	**740.**	**741.**	**742.**	**743.**
744.	**745.**	**746.**	**747.**	**748.**	**749.**	**750.**	**751.**
752.	**753.**	**754.**	**755.**	**756.**	**757.**	**758.**	**759.**

Annex B: Permitted marketing routes for RCDM


FARM CPH CURTILAGE
PERMITTED MARKETING ROUTES FOR THE SALE OF RAW COWS DRINKING MILK DIRECT TO THE FINAL CONSUMER FOR HUMAN CONSUMPTION
FARMERS MARKET EXTENSION OF THE FARM GATE
FARM GATE
MILK PRODUCTION HOLDING
B & B
CONSUMER INTERNET SALES
VENDING MACHINE
FARM SHOP
DISTRIBUTOR
DO NOT SELL TO CHILDREN, THE ELDERLY OR INDIVIDUALS WHO ARE IMMUNOCOMPROMISED
MILK MUST COMPLY WITH:
Regulation (EC) 178, Article 14 "food safety requirements", food must be safe
Regulation (EC) 2073/2005, Article 7 and Annex I, Chapter 1– ready to eat foods must comply with the "food safety criteria" e.g. limits for Listeria monocytogenes
The Food Safety and Hygiene (England) Regulations 2013 / The Food Hygiene (Wales) Regulations 2006, Schedule 6, limits for indicator organisms
Regulation (EC) 853/2004, Annex III, Section IX, Chapter I, Part III, 3 – for microbiological limits for plate count and somatic cell count