

**Oireachtas Joint Committee on Agriculture and the Marine**

**EU Regulation on Veterinary Medicinal Products EU 2019/6  
(Antibiotic stewardship in the Irish dairy industry)**

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23 March 2021

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**Summary**

- Antibiotic stewardship refers to the efforts made to ensure that antibiotics are used only when necessary and appropriate. Unless we limit antibiotic resistance, we will face a future without effective antibiotics.
- Progress in Ireland in antibiotic stewardship in food animal production is decades behind key international competitors.
- The need for intramammary antibiotic usage, both in-lactation and at drying off, will be reduced with improved on-farm mastitis control.
- Progress towards improved stewardship of intramammary antibiotics in Ireland is constrained by several past decisions and current policies.
- There is a need for detailed strategic planning and implementation to address key challenges to implementing improved antibiotic stewardship in Ireland
- The CellCheck Technical Working Group have outlined detailed recommendations for improved stewardship of intramammary antibiotics in a submission to the Veterinary Council of Ireland.

The purpose of this submission is to highlight key issues relevant to the Veterinary Medicines Regulation, with particular emphasis on intramammary antibiotics. It is critical that implementation in Ireland is in line both with scientific evidence and international best practice. The authors have considerable scientific expertise in this area.

### **There is a need for the highest standards in antibiotic stewardship in food animal production**

1. There is an urgent need to limit antibiotic resistance, a problem that is primarily being driven by the volume and nature of antibiotics that are being used in people and animals. If we are not successful, we will face a future without effective antibiotics.
2. Antibiotic stewardship refers to the efforts made to ensure that antibiotics are used only when necessary and appropriate. In food animal production, antibiotic stewardship refers to efforts:
  - a. to limit inappropriate usage, and
  - b. to optimise the choice, dose rate, route and duration of therapy to maximise clinical cures.

### **Progress in Ireland in antibiotic stewardship in food animal production is decades behind key international competitors**

3. Denmark and the Netherlands are examples of international best practice in antibiotic stewardship in farm animal production. These countries have introduced a range of measures to comprehensively address antibiotic usage in food animal production. As highlighted in [Table 1](#), the first of these measures was introduced in:
  - a. 1995, in Denmark
  - b. 2012, in the Netherlands
4. Ireland is many years behind Denmark and the Netherlands, introducing just one of the listed measures to maximise antibiotic stewardship, in 2018 (see [Table 1](#)).

5. Comparison between these three countries is justified<sup>1</sup>.

**Table 1. Comparison of antibiotic stewardship in farm animal production in Denmark, Ireland and the Netherlands.** The date of introduction of key national measures is presented

	Date of introduction		
	Denmark <sup>a</sup>	Ireland <sup>b</sup>	Netherlands <sup>c</sup>
Ban on prophylactic (preventive) use of antimicrobials	1995	-	2012
Decoupling of antimicrobial sales and profits	1995	-	-
Initial restrictions on the on-farm use of antimicrobial agents linked with veterinary oversight, including prescribed farm visits	1995 <sup>a</sup>	-	2014
Introduction of requirement for a one-to-one relationship between the farmer and the veterinarian	1995	-	2014
The first annual report of on-farm antimicrobial usage	1996	-	2012
The first treatment guidelines to support veterinary clinical decision-making	1996	-	2012
Mandatory reporting of farm prescribing/usage data to national database	2001	-	2012
The first restrictions (by industry or government) on the use of highest priority critically important antimicrobials (HP-CIAs) in food animals	2003	2018	2012
The first national target on reduction in antimicrobial usage	2010	-	2009
The introduction of farm-level benchmarking	2010	-	2012
Differential taxes on the sales of antimicrobials and other medicines for veterinary use	2013	-	-
The introduction of prescriber benchmarking	-	-	2012

a. Data from DANMAP annual reports. <https://www.danmap.org/reports>. DANMAP is the Danish Programme for surveillance of antimicrobial consumption and resistance in bacteria from food animals, food and humans

b. Information from iNAP, Ireland's National Action Plan on Antimicrobial Resistance 2017-2020. <https://www.gov.ie/en/publication/ec1fdf-irelands-national-action-plan-on-antimicrobial-resistance-2017-2020>

c. Data from Autoriteit Diergeneesmiddelen (Netherlands Veterinary Medicines Institute, SDA) annual reports. <https://www.autoriteitdiergeneesmiddelen.nl/en/publications/general-reports>  
 Voluntary from 1995, mandatory for larger farms from 2010

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<sup>1</sup> Denmark, Ireland and the Netherlands are each required to comply with the same EU legislation, and each have important national dairy industries with a not-dissimilar value and mix of dairy exports. In each country, dairy product quality is critical and all supply commodity for the manufacture of infant formula and other high value markets.

**The need for intramammary antibiotic usage, both in-lactation and at drying off, will be reduced with improved on-farm mastitis control**

6. Intramammary antibiotics (*the delivery of antibiotics into the udder through the teat canal*) are used in two situations:
- a. In-lactation (*whilst cows are being milked*), to treat known infected cows (therapeutic usage)
  - b. At drying off (*immediately following the last milking prior to the dry period*), either to treat known infected cows (therapeutic usage) or to prevent new infection in the dry period (prophylactic/preventive usage).

Treating all cows in a herd at drying off with antibiotic regardless of their infection status is known as blanket dry cow therapy (DCT), and will not be acceptable under the new regulations as it involves prophylactic/preventive usage. Irish farmers will be required to move towards selective DCT, whereby only animals with evidence of infection at drying off should receive antibiotic (therapeutic use). However, this transition is not without risk, particularly for herds where mastitis is not well controlled.

7. The need for intramammary antibiotics, both in-lactation and at drying off, is substantially reduced in herds with optimal mastitis control. Such herds will generally have a bulk tank milk SCC (somatic cell count) consistently below 200,000 cell/mL (noting that this is substantially lower than the regulatory limit of 400,000 cells/mL).

**Progress towards improved stewardship of intramammary antibiotics in Ireland is constrained by several past decisions and current policies**

Paragraphs 8, 9 and 10 below each provide examples of these past decisions.

8. In 2004, the EU introduced the Regulation (EC) No. 726/2004 which outlined procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human and veterinary use.

In response, Ireland introduced SI No. 786/2007 (subsequently replaced by SI No. 558/2017), which allowed intramammary antibiotic prescribing by a veterinarian without

the requirement for a herd visit at least every 12 months. Therefore, SI No. 786/2007 and SI No. 558/2017 have allowed remote prescribing of intramammary antibiotics since 2007, which has facilitated very limited veterinary oversight of these products. It is a substantial departure from international best-practice in antibiotic stewardship in food animal production (see [Table 1](#)).

SI No. 786/2007 and SI No. 558/2017 make reference to ‘a programme meeting the requirements of the Schedule’, the objective of which is ‘the prevention and treatment of clinical and subclinical bovine mastitis in a manner designed to minimise use of antibiotic treatments and, where necessary, set targets for a reduction in the number of mastitis cases for that herd’<sup>2</sup>. However, acting solely as a remote prescriber, it is unlikely that the veterinarian could address the following objectives, which are critical to sustainably resolving on-farm mastitis issues:

- A detailed understanding of the factors (including cause(s) and driver(s)) contributing to suboptimal mastitis control,
- A plan developed and agreed with the farmer to robustly and sustainably address each of these factors, including agreed actions, timelines and robust measures to monitor progress and antibiotic usage, and
- Ongoing and regular assessment and review.

The Food Safety Authority of Ireland does not support differential oversight of intramammary antibiotics in food animal production. In a 2015 report on antimicrobial resistance<sup>3</sup>, prior to the introduction of SI No. 558/2017, it was recommended by the Authority that prescribing controls be changed ‘to ensure that the level of veterinary supervision required in relation to use of antimicrobial agents in intramammary formulations is equivalent to the level that applies in most other prescribing scenarios’.

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<sup>2</sup> Statutory Instruments SI No. 558 of 2017. Animal health and welfare (Animal Remedies Veterinary Practice and Veterinary Medicine) Regulation 2017.

<http://www.irishstatutebook.ie/eli/2017/si/558/made/en/print>

<sup>3</sup> Potential for Transmission of Antimicrobial Resistance in the Food Chain. Report of the Scientific Committee of the Food Safety Authority of Ireland, 2015.

[https://www.fsai.ie/faq/antimicrobial\\_resistance.html](https://www.fsai.ie/faq/antimicrobial_resistance.html)

9. In 2004, the EU introduced Regulations 853/2004 and 854/2004 which outline requirements for the hygienic production of milk, including a requirement that raw milk has a 3-month rolling geometric mean SCC not exceeding 400,000 cells/mL.

In response, Ireland has adopted a system of data adjustment and interpretation for determining herd eligibility to supply raw milk for processing of dairy products<sup>4</sup>. Seven methods have been used, as explained in [Figure 1](#), with all but the seasonality formula still operating. In effect, this system (of data adjustment and interpretation) allows ongoing collection of milk from herds with bulk tank SCC exceeding 400,000 cells/mL.

10. The Bord Bia sustainable quality assurance programmes, including the Sustainable Dairy Assurance Scheme (SDAS), have been developed as a means to promote product quality to consumers. As suggested by Bord Bia, 'these programmes are built on best practice in farming and processing, current legislation, relevant industry guidelines and international standards - and are accredited to the ISO 17065/2012'<sup>5</sup>.

In reality, however, the SDAS standards with regards to SCC and mastitis control, each being key components of milk quality, do not exceed the legislative baseline<sup>6</sup>.

These three examples (from paragraphs 8, 9 and 10) illustrate past decisions and current policies, either directly or indirectly impacting on intramammary antibiotic prescribing and usage, that are constraining efforts towards improved antibiotic stewardship in the Irish dairy industry.

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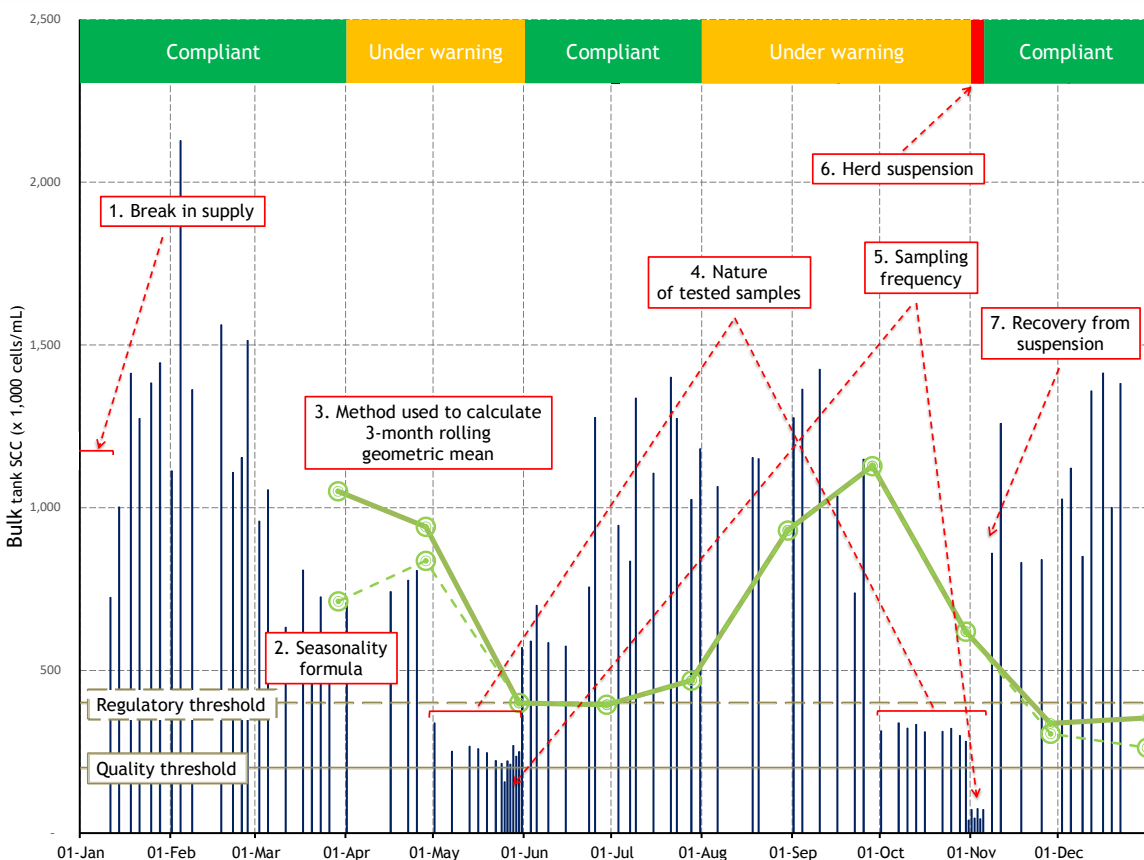
<sup>4</sup> More, S.J., Clegg, T.A., Lynch, P.J., O'Grady, L., 2013. The effect of somatic cell count data adjustment and interpretation, as outlined in European Union legislation, on herd eligibility to supply raw milk for processing of dairy products. *J Dairy Sci* 96, 3671–3681. <https://doi.org/10.3168/jds.2012-6182>

<sup>5</sup> <https://www.bordbia.ie/farmers-growers/get-involved/become-quality-assured/>

<sup>6</sup> More, S.J., Marchewka, J., Hanlon, A., Balzani, A., Boyle, L., submitted. An evaluation of four private animal health and welfare standards and associated quality assurance programmes for dairy cow production.

**Figure 1. The methods used in Ireland to determine herd eligibility to supply raw milk for processing of dairy products based on current rules of data adjustment and interpretation.**

This spring-calving Irish herd had an extremely high bulk tank somatic cell count (SCC) throughout lactation (see thin vertical bars). The annual unadjusted geometric mean was 1,000,000 cells/mL, after excluding periods of low SCC (indicated) in May, October and early November, yet the herd was eligible to supply (either 'compliant' [green] or 'under warning' [yellow]) except for 1 week in November [red]. The calculated 3-month rolling geometric mean SCC (somatic cell count) is presented as a thick lime green line, and the methods contributing to data adjustment and interpretation (1. to 7.) are indicated (further detail below). The regulatory and quality thresholds for SCC are 400,000 and 200,000 cells/mL, respectively



Data adjustment and interpretation applicable to Irish suppliers:

1. Break in supply of at least one calendar month, which allows the rolling geometric mean SCC to be reset
2. Application of the seasonality formula (withdrawn since November 2018).
3. Calculation of the 3-month rolling geometric mean. All data points are included (rather than the monthly geometric means), which allows points 4. and 5. (below) to be influential. Can only be calculated once 3 months of data are generated.
4. Nature of tested samples. Sampling may not be representative of the full milking herd.
5. Sampling frequency. Data stacking will substantially impact on calculation of 3-month rolling geometric mean.
6. Herd suspension. Independent validation is yet to be conducted.
7. Recovery from suspension: Lack of clarity around actions required to resolve milk quality issues on farm, and regain compliance.

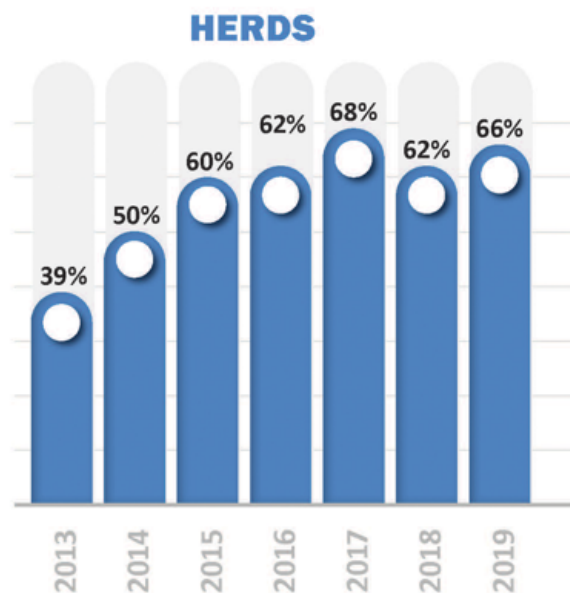
Herds are considered compliant during the months that the 3-month rolling geometric mean is <400,000 cell/mL and during the first month that this mean exceeds 400,000 cells/mL. A herd is under warning for a maximum of 3 months (from months 2-4) where this mean continues to exceed 400,000 cells/mL. A herd is suspended from the start of month 5 where this mean continues to exceed 400,000 cells/mL<sup>4</sup>.

That said, there are also some national decisions that have been very positive:

11. Established in late 2010, CellCheck is playing a critical role in supporting national improvement in mastitis control and milk quality<sup>7</sup>. It is being developed and delivered in partnership with industry bodies representing farmers, processors, service providers and government. CellCheck is coordinated by Animal Health Ireland. The udder health of the national herd has improved significantly over the last decade, based on key principles of creating awareness, establishing best practice, building capacity and setting goals ([Figure 2](#)). Further, there has been a fall over the last decade in the estimated on-farm usage of

**Figure 2. The percentage of herds with an annual unadjusted geometric mean SCC <200,000 cells/mL, by year.**

Therefore, 34% of Irish herds in 2019 had an annual unadjusted geometric mean SCC of 200,000 cells/mL or greater. Source: CellCheck



<sup>7</sup> Devitt, C., McKenzie, K., More, S.J., Heanue, K., McCoy, F., 2013. Opportunities and constraints to improving milk quality in Ireland: enabling change through collective action. *J Dairy Sci* 96, 2661–2670. <https://doi.org/10.3168/jds.2012-6001>



antibiotics used to treat mastitis during lactation, after accounting for the increase in the number of dairy cows nationally<sup>8,9</sup>.

12. *i*NAP is Ireland's national multisector action plan to tackle antimicrobial resistance. The first plan (2017-20) was conducted in conjunction with the Department of Health and the Environmental Protection Agency, and work is ongoing on a second plan from 2021.

**There is a need for detailed strategic planning and implementation to address key challenges to implementing improved antibiotic stewardship in Ireland**

13. Over recent decades, there have been mixed messages to Irish farmers about the importance of SCC standards. From a positive perspective, farmers are very aware of the important role that they play to ensure the quality of Irish dairy exports. There is strong awareness among farmers of the importance of on-farm mastitis control, and CellCheck is a respected national resource, including to assist farmers to resolve high SCC issues. However, these messages are not aligned with key policy instruments:

- a. Regulation: As a result of data adjustment and interpretation, it is possible for herds with very high SCC to continue to supply raw milk (see [Figure 1](#)).
- b. Bord Bia standards: No SCC standard is specified within the SDAS standards. With respect to SCC, farmers are required only to meet legal requirements<sup>10</sup>.

As a consequence, at least in part, there are ongoing milk quality issues across the national herd. In 2019, 34% of Irish dairy herds had an annual unadjusted geometric mean SCC above 200,000 cells/mL (generally recognised as the quality threshold) (see [Figure 2](#)). In these 5,000 or so herds, the new requirements under the Veterinary Medicines regulation will need to be introduced, under veterinary supervision, with considerable care.

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<sup>8</sup> More, S.J., Clegg, T.A., McCoy, F., 2017. The use of national-level data to describe trends in intramammary antimicrobial usage on Irish dairy farms from 2003 to 2015. *J Dairy Sci* 100, 6400–6413. <https://doi.org/10.3168/jds.2016-12068>

<sup>9</sup> McAloon, C., McCoy, F., More, S.J., under review. Trends in estimated intramammary antimicrobial usage in the Irish dairy industry from 2003-19. *JDS Commun*

<sup>10</sup> Sustainable Dairy Assurance Standard – Revision 01, December 2013. p18

14. There have also been mixed messages to farmers about the importance of antibiotic stewardship. SI No. 786/2007 and SI No. 558/2017 have introduced Irish farmers to very low levels of antibiotic stewardship and also to differing approaches to antibiotic stewardship according to administration route (for example, intramammary, intramuscular). Neither of these concepts is aligned to international best-practice. In 2015, an estimated 45% of in-lactation and 51% of dry cow tubes were sold in Ireland through remote prescribing<sup>8</sup>.
15. In order to safely deliver a national sustained reduction in antibiotic usage in the Irish dairy industry, there is a need for ongoing, parallel improvement in national milk quality, particularly in the 5,000 or so herds where the annual unadjusted geometric mean SCC is greater than 200,000 cells/mL.
16. A substantial shift in mindset and practice will be needed to enable farmers to safely move away from blanket DCT which is currently the norm in Ireland<sup>8,9</sup>.
17. Objective and transparent monitoring, national targets, benchmarking (nationally, of sectors, and of farms and prescribers) and independent research have been central to progress in competitor countries, both for improved SCC and reduced antibiotic usage. Annual reporting of on-farm antibiotic usage was first introduced in Denmark and the Netherlands in 1996 and 2012, respectively (Table 1). In Ireland, however:
  - a. Bulk tank SCC (which has been routinely collected by the Department of Agriculture, Food and the Marine since 2014) is not available for independent research in a form that lends itself to meaningful analysis.
  - b. Limited information about on-farm intramammary antibiotic usage is available, which is currently extrapolated from sales data<sup>8,9</sup>. However, robust analysis and monitoring of on-farm antibiotic usage relies on national systems for the capture of prescribing and usage data. These systems are currently under development in Ireland.
18. There is a need for broad representation from all relevant stakeholders in these discussions, including government, industry (food manufacturers and farmers), the veterinary and medical professions, and the general public (including consumers). Regulatory capture<sup>7</sup> must be avoided.

19. It is crucial that national policy discussions and decision-making are supported by the best-available science, including robust evidence.
20. Examples of best-practice from Denmark and the Netherlands highlight the need for detailed strategic planning and implementation. In all cases, decision-making is driven by the primary objective to improve antibiotic stewardship and limit antibiotic usage in the dairy industry. In these countries, roll-out has been undertaken over a series of years, supported by ongoing monitoring, transparent reporting and review. Detailed yearly national reports from these countries is available, from Denmark since 1996<sup>11</sup> and from the Netherlands since 2012<sup>12</sup>.

**The CellCheck Technical Working Group have outlined detailed recommendations for improved stewardship of intramammary antibiotics in a submission to the Veterinary Council of Ireland**

21. The CellCheck Technical Working Group has presented a detailed submission to the Veterinary Council of Ireland (VCI) in relation to the Veterinary Medicines regulation. These are guidelines for the prescribing of intramammary antibiotics, drawing on international best-practice but adapted to the challenges currently facing Ireland.
22. In brief, the submission highlights the need for the prescriber to have the following information in support of dry cow therapy (*antibiotics administered at drying off*):
  - a. Animal-level information to allow ongoing assessment of all lactating cows
  - b. Herd-level information, in particular a sophisticated understanding of the farm, including the herd, the people, the facilities and farm management. As clearly articulated in Article 107(1) of 2019/6, antimicrobial medicinal products should not be applied routinely nor used to compensate for poor hygiene, inadequate animal husbandry or lack of care or to compensate for poor farm management.

A shift from blanket to selective dry cow therapy, as required under the regulation, will not be possible without individual animal-level information. Milk recording is preferred due to

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<sup>11</sup> <https://www.danmap.org/reports>

<sup>12</sup> <https://www.autoriteitdieregenesmiddelen.nl/en/publications/general-reports>

the relative practicality of delivery and the multiple additional benefits to farm management.

23. In brief, the submission highlights the need for the prescriber to have the following information in support of in-lactation therapy (*antibiotics administered during milking*):
- a. Animal-level information to allow individual assessment of specific cows with clinical or subclinical mastitis
  - b. Herd-level information, as above. There is also the need a detailed understanding of the mastitis pathogen challenge and the antibiotic resistance patterns on the farm.
24. In addition, a comprehensive and coordinated range of national actions are required to facilitate optimal mastitis control and responsible prescribing across all Irish dairy farms. The following measures (which is not a comprehensive list of the measures recommended in the VCI submission) have either been adopted by international competitors, often decades previously, or are specific to current constraints in Ireland:
- a. A single prescriber (or prescribing practice) per farm to ensure knowledge/oversight of all antibiotics prescribed and used, and a holistic and coherent understanding of the rationale and strategy for antibiotic prescribing and use.
  - b. Ongoing education and training of prescribers
  - c. Objective and transparent monitoring of on-farm antibiotic usage, and national targets, benchmarking (both of farms and prescribers) and independent research
  - d. Restriction/bans on specific antibiotics
  - e. Ongoing support for farm-level mastitis control, through farmer education, farmer peer learning through discussion groups, supportive milk pricing structures, and technological developments
  - f. Redrafting of current approaches to SCC data adjustment and interpretation
  - g. Redrafting of the Bord Bia standards to facilitate improved milk quality

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