DIRECTION UNDER REGULATION 21 OF THE EUROPEAN COMMUNITIES (CONTROL OF ANIMAL REMEDIES AND THEIR RESIDUES) REGULATIONS 2009 (Milk Sector).

1. The Minister for Agriculture, Food and the Marine, in exercise of the powers conferred by Regulation 21(2) of the European Communities (Control of Animal Remedies and Their Residues) Regulations 2009 (S.I. No 183 of 2009), hereby directs –

   «Company», «Address_1», «Address_2», «Address_3»

   that the plan for the detection of residues of substances, veterinary medicines and contaminants, referred to in Annex I to Council Directive 96/23/EC of 29 April, 1996 ('Self-monitoring residue plan') to be implemented at –

   «Company», «Address_1», «Address_2», «Address_3»

   shall, as a minimum and without prejudice to any risk assessment carried out by the company concerned, comply with the requirements specified in Parts I-III of this Direction.

2. A Self-monitoring Residue Plan is aimed at protecting consumers from residue hazards in foods of animal origin by providing the food business operator with the means of satisfying him/herself that food of animal origin presented for processing at the premises to which a plan relates do not contain animal remedies, the administration of which is prohibited to animals or residues of authorised animal remedies or contaminants in excess of maximum permitted levels.

3. It should be noted that, where a food business operator[1] receives milk for processing from another purchaser, that primary purchaser is responsible for ensuring that the appropriate levels of monitoring are carried out on the milk from the farm concerned. In this context, the food business operators concerned should have appropriate arrangements in place, including arrangements for transfer of information about previous positive results.

4. It is the responsibility of the food business operator to whom this direction is addressed to take appropriate steps so that their suppliers of animal products are aware of these arrangements.

5. A person who submits a Self-monitoring residues plan arising from this Direction shall implement the plan as submitted; where it is proposed to amend the plan, DAFM shall be notified in advance.

6. This Direction applies from 1st January 2016.

'Food business operator' means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

PART I

FORMAT OF SELF-MONITORING RESIDUE PLAN

The format of the Self-monitoring residue plan shall comply with **SCHEDULE 1 & 2** (including the declarations contained in those Schedules) to this Direction.

PART II

SAMPLING LEVELS AND FREQUENCY

Without prejudice to the responsibility of a person submitting a Self monitoring residue plan to determine, in accordance with a risk assessment strategy, the range of substances to be checked, the self-monitoring residue plan shall, as a minimum, cover the range of substances and minimum levels specified in Section A below:

Section A

Group B (1)

Samples shall be taken from consignments of milk in such a manner to ensure that at least 10% of persons who supply milk to the plant to which the plan relates are subject to testing. In the event that more than the minimum 10% are sampled, results in respect of all samples must be reported under your Self Monitoring plan and in the case of positive results, the measures set out in Section B must be followed.

Samples shall be analysed to detect **all antibiotic groups**.

Group B (3)

Samples shall be taken from consignments of milk in a manner to ensure that 0.75% of the persons who supply milk to which the plan relates are subject to testing.

As a minimum, samples shall be analysed to detect the presence of pesticides.

Section B

Measures to be taken where a sample is found to be positive.

(Note: The measures laid down in this Section are minimum actions that must be taken in the circumstances outlined and are without prejudice to more stringent measures implemented by the person submitting the plan).

1. Where:
   - (i) a positive result is detected arising from analysis of a sample taken under the self monitoring residue plan implemented on the basis of this Direction,
   - (ii) the milk processor is notified of a positive result detected by another milk processor, or
   - (iii) the milk processor is notified of a positive result of one of the Group B1 or Group B3 substances specified in Section A, detected under the DAFM National Residue Plan,

   (hereinafter referred to as 'a positive sample') the following procedure shall apply:

   (a) The supplier concerned shall not supply milk until a sample taken from a consignment of milk presented by him or on his behalf tests negative for the substance or group of substances in respect of which the positive finding was made.

   (b) For a period of at least 30 days from the date of the negative test result at (a) becomes available, a sample shall be taken from <u>each</u> consignment of milk presented by the supplier or on his behalf and tested for the substance or group of substances in respect of which the positive finding was made.

   (c) In the event of a 2nd positive during this 30 day period the provisions at (a) above apply i.e. the supplier concerned shall not supply milk until a sample taken from a consignment of milk presented by him or on his behalf tests negative for the substance or group of substances in respect of which the positive finding was made.

   (d) For a second period of at least 30 days from the date of the negative test result at (c) becomes available, a sample shall be taken from <u>each</u> consignment of milk presented by the supplier or on his behalf and tested for the substance or group of substances in respect of which the positive finding was made.

2. In the event of a 3rd positive arising from paragraph 1, for a period commencing on the date the 3rd positive result becomes available, in respect of the next six months deliveries, a sample shall be taken from <u>each</u> consignment of milk presented by the supplier or on his behalf and tested for the substance or group of substances in respect of which the positive finding was made.

3. Where samples are taken pursuant to Paragraph 2, each consignment of milk from which samples [a]re derived is to be **detained** pending the results of analysis becoming available.

4. If there is a positive result from analysis as provided for in Paragraphs 1, 2 or 3 of this Section (other than follow up samples taken to achieve a negative status at paragraph 1(a), the following areas of DAFM shall be informed within 24 hours of the details of the positive result (i.e. the name, address, Creamery/Supplier Number and herd number of the owner of the animal).

   - The Dairy Produce Inspector and the Veterinary Inspector in Charge of the premises, and
   - The Veterinary Medicines Section,
     Department of Agriculture, Food and the Marine
     Administration Building
     Backweston Campus
     Youngs Cross
     Celbridge
     Co Kildare
     (Email: carmel.ogrady@agriculture.gov.ie or cillian.hegarty@agriculture.gov.ie
     or Fax 01 6102659)

5. The measures to be undertaken in accordance with Section B are additional to and not in substitution for the measures laid down in Section A.

Section C – Procedures applicable to taking of samples.

1. Samples shall be taken only from raw milk

2. Each sample may be analysed for detecting the presence of one or more substances while respecting the total number of samples to be tested.

3. Taking and analysis of samples should reflect the profile of production at the premises to which this direction relates.

4. Samples shall be taken in such a manner to ensure that the taking of samples is affected at no fixed time and on no particular day of the week.

5. Samples shall be representative and of sufficient size to allow adequate analysis of the substance under investigation.

6. Sampling shall be targeted taking account of all available background information and any evidence of misuse or abuse of substances.

7. Samples shall be collected in suitable containers to ensure sample integrity and traceability and all measures shall be taken to prevent substitution, cross-contamination and degradation.

PART III

LABORATORIES

1. Samples shall be analysed at a laboratory, which has the relevant expertise and can demonstrate competence in the analysis of the substance or substances under investigation and that operates an appropriate quality control system.

2. **Analysis shall be performed using validated methods of analysis that conform to the criteria laid down in Commission Decision 2002/657/EC.**

3. A laboratory engaged in analysis shall have appropriately qualified staff and suitable equipment to ensure the validity of any analytical result.

4. A laboratory engaged in analysis shall implement an appropriate quality assurance scheme based on good laboratory practice principles (**at least to the standard of ISO 17025**) and shall take appropriate measures to demonstrate the validity of its analytical data including participating in proficiency testing programmes.

5. A laboratory engaged in analysis shall participate in such tests, including analysis of samples, as may be directed by the National Reference Laboratory from time to time.

6. A laboratory engaged in analysis shall maintain records of analysis for a period of at least seven years and make same available on demand to an authorised officer or an officer of the National Reference Laboratory.

Dated this 12 day of November 2015

_____

An officer authorised in that behalf by the Minister
for Agriculture, Food and the Marine

SCHEDULE 1

TEMPLATE FOR SELF-MONITORING RESIDUE PLAN 2016

Company Name: _____

Address: _____

Phone no. & email:

_____

Person responsible for the plan:

_____

Phone no. & email of responsible person

Number of Milk Suppliers: _____

Details of Processing Plant/Co-Op to which this plan relates[2]:

Name	Establishment Approval Number

Species of Animal	Group of Substances	Compounds	Matrix	Laboratory Method[3]	Limit of Detection	Level Of Action	Proposed No of Samples	Laboratory

[2] Including milk purchasers on whose behalf milk is processed

[3] Only Laboratory Methods and Limits of Detection at least equivalent to those listed in Schedule 2 should be used.

DECLARATION BY PERSON IN CHARGE OF SELF- MONITORING PROGRAMME 2016

1. I hereby confirm that the plant has a contract with:

Name of Laboratory/Laboratories

_____

_____

_____

to carry out analysis of samples on our behalf under a plan submitted pursuant to Regulation 21 of the European Communities (Control of Animal Remedies and Their Residues) Regulations 2009[1].

2. The attached Standard Operation Procedure[2] is in place at the plant in relation to follow up procedures where a positive residue is found, including detention of consignments of milk.

Name of Processing Plant/Co-Op:

_____

Signature of person in charge of Self Monitoring Plan:

_____

Position held in Company:

_____

Date: _____

Footnotes:
1. Copy of Declaration of Compliance by laboratories as per Declaration (DCL1) attached to be enclosed with the Plan.
2. Copy of Standard Operation Procedure to be enclosed with the Plan.

(Schedule 1 contd.)

DECLARATION OF COMPLIANCE BY LABORATORY (DCL 1) 2016

Name & Address of Laboratory:

I hereby declare that:

1. This laboratory has the relevant expertise and can demonstrate competence in the analysis of the substance or substances under investigation and operates an appropriate quality control system.

2**. Analysis shall be performed using validated methods of analysis that conform to the criteria laid down in Commission Decision 2002/657/EC**.

3. This laboratory has appropriately qualified staff and suitable equipment to ensure the validity of any analytical result.

4. This laboratory shall implement an appropriate quality assurance scheme based on good laboratory practice principles **(at least to the standard of ISO 17025**) and shall take appropriate measures to demonstrate the validity of its analytical data including participating in proficiency testing programmes.

5. A laboratory engaged in analysis shall maintain records of analysis for a period of at least seven years and make same available on demand to an authorised officer or an officer of the National Reference laboratory.

I further undertake that where the above laboratory is engaged in analysis under a plan submitted by:

Name of Processing Plant/Co-Op:

---

pursuant to Regulation 21 of the European Communities (Control of Animal Remedies and Their Residues) Regulations 2009 it shall participate in such tests, including analysis of samples as may be directed by the National Reference Laboratory from time to time.

Signed: _____

Position held at Laboratory: _____

Date: _____

Schedule 2

Reference Laboratory Methods & Detection Levels

Species	Substance	Laboratory Method	Detection Levels
Milk	Antibiotics:	2 plate & Charm test	MRL*(if fixed)
	Pesticides	GCMS	MRL*/ML** (if fixed)

* MRLs fixed for pharmacologically active substances are listed in Commission Regulation 37/2010 and for certain coccidiostats in Commission Regulations 885/2010 and 875/2010.

** MLs for certain coccidiostats are listed in Commission Regulation 124/2009.