Regulations and other Acts

Gouvernement du Québec

O.C. 1443-2022, 3 August 2022

Animal Health Protection Act
(chapter P-42)

Medicinal premixes and medicinal foods for animals
— Amendment

Regulation to amend the Regulation respecting medicinal premixes and medicinal foods for animals

WHEREAS, under subparagraph 1 of the first paragraph of section 55.9 of the Animal Health Protection Act (chapter P-42), the Government may make regulations to prescribe conditions for the issue and renewal of permits, the form of permits and the fees therefor;

WHEREAS, under subparagraph 3 of the first paragraph of section 55.9 of the Act, the Government may make regulations to prescribe the books, accounts, registers and other documents to be maintained and kept by a permit holder and the place where the permit holder must keep them, the reports the permit holder must make to the Minister, the information the reports must contain and the time when they must be filed;

WHEREAS, under subparagraph 4 of the first paragraph of section 55.9 of the Act, the Government may make regulations to prescribe standards applicable to the organization, management and operation of any establishment operated under a permit;

WHEREAS, under subparagraph 10 of the first paragraph of section 55.9 of the Act, the Government may make regulations in particular to prescribe methods, conditions and modalities respecting the taking and analysis of samples of a medication, medicinal premix or medicinal food or of any substance taken from an animal and determine where the sample or specimen must be sent for analysis;

WHEREAS, under subparagraph 11 of the first paragraph of section 55.9 of the Act, the Government may make regulations to determine, among the provisions of a regulation passed under that section, those provisions the contravention of which is punishable under section 55.43 of the Act;

WHEREAS the Government made the Regulation respecting medicinal premixes and medicinal foods for animals (chapter P-42, r. 10);

WHEREAS, in accordance with sections 10 and 11 of the Regulations Act (chapter R-18.1) and the second paragraph of section 55.9 of the Animal Health Protection Act, a draft Regulation to amend the Regulation respecting medicinal premixes and medicinal foods for animals was published in Part 2 of the *Gazette officielle du Québec* of 2 February 2022 with a notice that it could be made by the Government on the expiry of 45 days following that publication;

WHEREAS it is expedient to make the Regulation with amendments;

IT IS ORDERED, therefore, on the recommendation of the Minister of Agriculture, Fisheries and Food:

THAT the Regulation to amend the Regulation respecting medicinal premixes and medicinal foods for animals, attached to this Order in Council, be made.

YVES OUELLET
Clerk of the Conseil exécutif

Regulation to amend the Regulation respecting medicinal premixes and medicinal foods for animals

Animal Health Protection Act
(chapter P-42, s. 55.9, 1st par., subpars. 1, 3, 4, 10 and 11)

1. The Regulation respecting medicinal premixes and medicinal foods for animals (chapter P-42, r. 10) is amended in section 2

(1) by inserting "for the permit holder's own animals or animals in his custody" at the end of paragraph 2;

(2) by inserting "for the permit holder's own animals or animals in his custody" at the end of paragraph 3.

2. Section 4.1 is replaced by the following:

"**4.1.** To obtain a permit, the applicant must have premises and containers that prevent all chemical, biological or physical contamination of medicines, medicinal premixes and medicinal foods.

In the case of a permit referred to in any of paragraphs 2 to 4 of section 2, the applicant must, in addition, have equipment that complies with the provisions of section 5.

4.1.1. The Minister shall issue a permit to an applicant who meets the conditions set out in the first paragraph and, where applicable, the second paragraph of section 4.1. The permit application must be submitted using the form prescribed by the Minister, on which the applicant must enter

(1) his name, address, telephone number and, where applicable, email address or fax number; that information is also required from the applicant's representative, if any;

(2) the applicant's Québec business number assigned under the Act respecting the legal publicity of enterprises (chapter P-44.1), where applicable;

(3) the name under which the establishment is operated;

(4) the address of the place of operation;

(5) the nature of the permit applied for; and

(6) in the case of a permit referred to in paragraphs 2 to 4 of section 2, a description of

(*a*) the equipment that will come into contact with a medicine, a medicinal premix or a medicinal food; and

(*b*) the mixing equipment and, where applicable, of the scales, specifying the serial number, make and model.

The applicant must declare in the application that the premises and containers and, where applicable, equipment comply with the provisions of section 4.1.".

3. Section 4.2 is revoked.

4. Section 4.3 is replaced by the following:

"**4.3.** The Minister shall renew the permit of a holder who applies for renewal using the form prescribed by the Minister, on which the holder must

(1) indicate, where applicable, any change in the information provided pursuant to section 4.1.1 for the last application;

(2) declare having kept and sent, for the preceding calendar year, the registers provided for in section 14 or 15, as the case may be, and in the case of the register provided for in section 23.1, declare having kept the register; and

(3) in the case of a permit referred to in any of paragraphs 2 to 4 of section 2, provide the information listed in subparagraphs 1 to 7 of the first paragraph of section 9 establishing that the mixing equipment provides homogeneous distribution of medicines in accordance with the provisions of section 8.

The fees specified in section 2 must be included with the application.".

5. Section 4.5 is revoked.

6. The heading of Division II is amended by striking out "ORGANIZATION, MAINTENANCE AND".

7. Section 5 is replaced by the following:

"**5.** The equipment used by a permit holder for the preparation of a medicinal premix or medicinal food must

(1) be made of non-rotting, waterproof, non-toxic materials; and

(2) be so designed that no residue is left after use.

The equipment must also allow any parts coming into contact with a medicine, a medicinal premix or a medicinal food to be inspected from the interior.".

8. The third paragraph of section 8 is replaced by the following:

"**8.** The coefficient of variation is calculated using the results of an analysis of 9 samples taken from the medicinal premix or the medicinal food by a member of a professional order defined in section 1 of the Professional Code (chapter C-26) practising in an area related to the production of medicinal premixes or medicinal foods or to inspection of equipment covered by this Division, using one of the methods provided for in section 28, 29 or 30, as the case may be. The samples must be sent for analysis in accordance with section 30.1.

The coefficient of variation is calculated using the results of an analysis of 9 samples taken from the medicinal premix or the medicinal food by a member of a professional order defined in section 1 of the Professional Code (chapter C-26) practising in a field of practice connected to the production of medicinal premixes or medicinal foods or the verification of equipment referred to in this Division, using one of the methods provided for in section 28, 29 or 30, as the case may be. The samples must be sent for analysis in accordance with the provisions of sections 30.1 and 30.2.

The mixing equipment used for the preparation of a medicinal premix or medicinal food must be inspected annually to ensure the homogeneity of the medicines it contains. The compliance of such equipment is verified through a chemical analysis of the medicine contained in the medicinal premix or medicinal food.".

9. Sections 9, 10, 11 and 12 are replaced by the following:

"**9.** The holder of a permit must submit to the Minister, with the holder's application for renewal, the following information on the verification of his mixing equipment:

(1) the identification of the mixing equipment including its serial number, make and model;

(2) the type of mix prepared;

(3) the trade name of the medicine and its concentration;

(4) the place of sampling and sampling method used for the 9 samples provided for in any of sections 28, 29 and 30;

(5) the mixing time in minutes and seconds and the duration of the mixing time from the addition of the last ingredient and the beginning of emptying;

(6) the name of the laboratory where the samples were sent and the analytic method used;

(7) the coefficient of variation as a percentage.

The permit holder must also, within 3 months of the date of issue of his permit, forward to the Minister the information provided for in subparagraphs 1 to 7 of the first paragraph.

The permit holder must keep the information in the place of operation covered by the permit for a period of 2 years.

10. The holder of a permit may not prepare, supply or sell a medicinal premix having a medicinal strength in each of its parts that is more than 10% lower or higher than the strength prescribed by prescription of a veterinary surgeon or, failing such prescription, by the Compendium of Medicating Ingredient Brochures published by the Canadian Food Inspection Agency.

11. Furthermore, the holder of a permit may not prepare, supply or sell a medicinal food

(1) having a strength in antibiotics of each of its parts that is more than 25% lower or higher than the strength prescribed by prescription of a veterinary surgeon or, failing such prescription, by the Compendium of Medicating Ingredient Brochures; or

(2) having a strength in any other medicine of each of its parts that is more than 20% lower or higher than the strength prescribed by prescription of a veterinary surgeon or, failing such prescription, by the Compendium of Medicating Ingredient Brochures.

12. The holder of a permit shall obtain the vouchers for all purchases of medicines, medicinal premixes or medicinal foods and keep them at the place of operation covered by the permit for a period of 2 years from the date of purchase.".

10. Section 13 is amended

(1) by inserting ", in the place of operation covered by the permit," after "keep";

(2) by replacing "1 year" by "2 years".

11. Sections 14 and 15 are replaced by the following:

"**14.** The holder of a permit shall keep a register of retail sales and supplies of medicinal foods showing, for each sale or supply,

(1) the name and address of the purchaser or person receiving the medicinal food, along with his permit number, if any;

(2) the address of the sites where the medicinal foods were sold or supplied, if different from the address referred to in subparagraph 1.

The register must contain the following information for each site:

(1) the date of the sale or supply;

(2) the trade name and concentration, in kilograms per tonne, of the medicinal products contained in the medicinal food;

(3) the name of the veterinary surgeon who prescribed the medicinal food, the number of his operating permit and the date of the prescription in the case of a medicinal food containing a medication appearing on the list provided for in section 9 of the Veterinary Surgeons Act (chapter M-8);

(4) the quantity, in kilograms, of the medicinal food sold or supplied;

(5) the animal species, number and age of the animals for which the medicinal food is intended and the types of agricultural production involved.

A permit holder who administers a medicinal food to his own animals or to animals in his custody must also keep a register of the medicinal foods administered. The second paragraph applies, with the necessary modifications, to the keeping of the register.

The registers must be kept for the period between 1 January and 31 December and be forwarded to the Minister not later than 31 March each year. They must be kept at the place of operation covered by the permit for a period of 2 years as of 31 December of the year concerned.

15. The permit holder shall also keep a register of sales and supplies showing each sale and supply of medicinal premixes made to the holder of a permit referred to in any of subdivisions 3 and 4 of this Division and containing

(1) the name and address of the purchaser or person receiving the medicinal premix along with his permit number; and

(2) the address of the sites where the medicinal foods prepared using medicinal premixes will be administered, if different from the address referred to in subparagraph 1 of this paragraph.

The register must contain the following information for each site:

(1) the date of the sale or supply;

(2) the trade name and concentration, in kilograms per tonne, of the medicinal products contained in the medicinal premix;

(3) the name of the veterinary surgeon who prescribed the medicinal premix, the number of his operating permit and the date of the prescription in the case of a medicinal premix containing a medication appearing on the list provided for in section 9 of the Veterinary Surgeons Act (chapter M□8);

(4) the quantity, in kilograms, of the medicinal premixes sold or supplied;

(5) the animal species, number and age of the animals for which the medicinal food that will be prepared later using the premix is intended, and the types of agricultural production involved.

The register must be kept for the period between 1 January and 31 December and be forwarded to the Minister not later than 31 March each year. It must be kept at the place of operation covered by the permit for a period of 2 years as of 31 December of the year concerned.".

12. Section 16.1 is revoked.

13. Section 16.2 is amended by striking out "14 and".

14. The heading of subdivision 3 of Division II is amended by adding "intended for the permit holder's own animals or animals in his custody" at the end.

15. Sections 20 to 22 are revoked.

16. Section 23 is amended

(1) by striking out "and shall keep such vouchers for 2 years from the date of the purchase" at the end of the second paragraph;

(2) by adding the following paragraph at the end:

"The documents referred to in the first and second paragraphs must be kept at the place of operation covered by the permit for a period of 2 years from the date of the prescription or purchase, as the case may be.".

17. The following is inserted after section 23:

"**23.1.** The holder of a permit shall keep a register of the medicinal foods administered to the holder's own animals or to animals in his custody, indicating the address of the sites where the animals receiving the foods are located. The register must contain the following information for each site:

(1) the date of administration;

(2) the trade name and concentration, in kilograms per tonne, of the medicinal products contained in the medicinal food administered;

(3) the name of the veterinary surgeon who prescribed the medicinal foods, the number of his operating permit and the date of the prescription in the case of a medicinal food containing a medication appearing on the list provided for in section 9 of the Veterinary Surgeons Act (chapter M-8);

(4) the quantity of the medicinal food administered;

(5) the animal species, number and age of the animals for which the medicinal food is intended, and the types of agricultural production involved.

The register must be kept at the place of operation covered by the permit for a period of 2 years following the date of administration.".

18. Section 24 is revoked.

19. Section 25 is amended by replacing "7, 8.1, 12" by "11".

20. The heading of subdivision 4 of Division II is amended by adding "intended for the permit holder's own animals or animals in his custody" at the end.

21. Section 25.1 is amended by replacing "8, 8.1, 10, 12, 16, 21 and 22" by "13, 16 and 23.1".

22. Sections 25.2 to 27 are revoked.

23. Sections 30.1 and 30.2 are replaced by the following:

"**30.1.** The 9 samples taken must be sealed and labelled to identify the permit holder and equipment concerned, and the number of each sample.

The samples must be sent to a laboratory to determine the coefficient of variation in accordance with section 8.

30.2. The holder of a permit is required to keep the laboratory analysis results at the place of operation covered by the permit for a period of 2 years.".

24. Division III.1, comprising sections 30.3 to 30.6, is revoked

25. The heading of Division IV is replaced by "OFFENCES".

26. Section 31 is amended by replacing "20 to 30" by "23 to 30.2".

27. Schedules II to VIII are revoked.

28. This Regulation comes into force on 1 January 2023.

105932

Gouvernement du Québec

O.C. 1451-2022, 3 August 2022

Act respecting the Régie de l'énergie
(chapter R-6.01)

1,000-megawatt block of wind energy

Regulation respecting a 1,000-megawatt block of wind energy

WHEREAS, under subparagraph 2.1 of the first paragraph of section 112 of the Act respecting the Régie de l'énergie (chapter R-6.01), the Government may make regulations determining, for a particular source of electric power supply, the corresponding energy block and maximum price established for the purpose of fixing the cost of electric power referred to in section 52.2 or for the purposes of the supply plan provided for in section 72, or for the purposes of a tender solicitation by the electric power distributor under section 74.1 of the Act;

WHEREAS, under subparagraph 2.2 of the first paragraph of section 112 of the Act, the Government may make regulations determining the timeframe applicable to a public tender solicitation by the electric power distributor under section 74.1 of the Act;

WHEREAS, in accordance with sections 10 and 11 of the Regulations Act (chapter R-18.1), a draft Regulation respecting a 1,000-megawatt block of wind energy was published in Part 2 of the *Gazette officielle du Québec* of 27 April 2022 with a notice that it could be made by the Government on the expiry of 45 days following that publication;

WHEREAS it is expedient to make the Regulation without amendment;

IT IS ORDERED, therefore, on the recommendation of the Minister of Energy and Natural Resources:

THAT the Regulation respecting a 1,000-megawatt block of wind energy, attached to this Order in Council, be made.

YVES OUELLET
Clerk of the Conseil exécutif