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For the Atten. Of
Mr A. Goodman
MSD Animal Health
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Our ref:
Your ref:
Date: 15/01/2018

Dear Mr. Goodman,

My apologies for the delay in writing back to you following the meeting on your Milton Keynes site on the 13th of December 2017.

The guidance note RGN2 version 3 gives the three tests, all of which must be satisfied for a plant to be considered under the Environmental Permitting Regulations 2017 as a chemical plant in which a chemical process is conducted. These criteria are detailed in Note 1 below.

It is my belief that the process conducted at your Milton Keynes plant fulfils these criteria and as such requires you to apply for a permit under these regulations.

The application forms are available on the Environment Agencies web site at <https://www.gov.uk/government/organisations/environment-agency> the permitting process is detailed in the main section Permits and Exceptions.

Yours Sincerely

A handwritten signature in black ink, appearing to read "David Howard".

David Howard
Regulatory Inspector
Tel. 02030255978
Email; david.howard@environment-Agency.gov.uk
Environment Agency | Bromholme Lane, Brampton, Huntingdon, PE28 4NE



INVESTOR IN PEOPLE



Note 1: Extract from RGN2

Note 4.0: All three of the tests in Notes 4.1, 4.2 and 4.3 must be met for an activity to meet the requirement to be "producing".

Note 4.1: Chemical Processing:

"Chemical Processing" should be taken to mean that a chemical reaction takes place as a fundamental part of the activity. Mixing substances which do not chemically react should not be considered as chemical processing, nor should simple adjustment of pH following a formulation operation or mixing operations (often to finish a product) where some minor incidental reactions do occur.

In this context "incidental" means:

- (a) only a small mass or molar proportion of the substances in the mixture are involved in any chemical reaction (after discounting water or other solvent) ; and*
- (b) any products of such a reaction remain in the mixture and are not separated, extracted, or released to the environment;*

Examples of incidental reactions in mixing operations are ones which change the physical characteristics of a formulation, such as viscosity, or adjusting the pH to a consumer-acceptable value.

Note 4.2: Chemical Plant

"Chemical Plant" should be taken to mean industrial plant and machinery (i.e. not domestic equipment) which is designed and constructed for the containment and control of the chemical reaction(s) that takes place as part of the chemical process. A reaction vessel would normally constitute "chemical plant" whereas a reaction on an open surface Environment Agency RGN 2 Appendices 1 and 2 42

Note 4.3: Commercial Purposes

"Commercial purposes" means conducting an activity, alone or with another activity, to meet a demand from another organisation or person for the chemical produced and receiving financial payment for it. An exception arises where the demand comes from market testing in which case, even though there may be no direct financial payment for it, the production activity is regarded as constituting "commercial purposes" since there is a clear intention to proceed to commercial sales subject only to the outcome of the test.

From: [Howard, David R](#)
To: [Goodman, A \(Ashley\)](#)
Cc: [Mintern, Sara](#)
Subject: Re: Environmental Permitting Application - MSD Animal Health, Milton Keynes
Date: 01 February 2018 05:55:39
Attachments: [image001.png](#)

EXTERNAL EMAIL – Use caution with any links or file attachments.

Hi Ashley

The regulations mention the use of fermentation as a process needing a permit but the main reaction I was considering was the surface reaction where the vaccine is turned off.

Hope this helps if you need any further clarification please contact me

Yours

David

Sent from my iPhone

On 31 Jan 2018, at 17:11, Goodman, A (Ashley) <ashley.goodman@merck.com> wrote:

Proprietary

Hello David,

Thank you for your letter dated 15 January 2018 recommending that an application for an environmental permit be made. I have scheduled a meeting with colleagues in Europe and the U.S. for next week to assist us with starting the process.

It would be useful to know whether the parasitic vaccine production (produced in chickens) or the bacterial fermentation production, explicitly triggered the “chemical processing” and if any one product flow did.

If I have any further questions and to keep you updated with status, I will be contact again.

Kind Regards

Ashley

Ashley Goodman

Safety, Health & Environment Manager

<image001.png>

MSD Animal Health

Walton Manor, Walton, Milton Keynes MK7 7AJ, UK

ashley.goodman@merck.com

T +44 (0)1908 685342

F +44 (0)1908 685608

msd-animal-health.co.uk



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