

Dear Mr. Rossignol,

Many thanks for your message. Due to the holiday season and some miscommunication at our side we did not include one other important issue. Would you be so kind to include the following remark as well?

Art. 95. and 13.5.

"Upgrading" of unclassified variations

Unclassified variations submitted as type IB can be reclassified as type II by the authorities.

How is it going to work? A new application including additional data is going to be requested? Would this also mean a delay in the procedure?

Many thanks in advance,

Kind regards,

Rob Joosten

2008/1/4, [Nicolas.ROSSIGNOL@ec.europa.eu](mailto:Nicolas.ROSSIGNOL@ec.europa.eu) <[Nicolas.ROSSIGNOL@ec.europa.eu](mailto:Nicolas.ROSSIGNOL@ec.europa.eu)>:  
Dear Dr. Joosten,

Thank you for your contribution to this public consultation. As usual, if you do not disagree your contribution will be published on our website after the end of the consultation period. You will also receive a summary of all comments.

The impact assessment accompanying the final Commission proposal will also outline how all contributions were taken into account.

With best regards,

Nicolas Rossignol

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**De:** [eggvporg@gmail.com](mailto:eggvporg@gmail.com) de la part de EGGVP

**Date:** ven. 4/01/2008 17:02

**À:** ROSSIGNOL Nicolas (ENTR)

**Objet :** Re: Revision of the Variations Regulations: launch of public consultation on the 'comitology' part

Dear Mr Rossignol,

Please find attached the EGGVP comments.

Kind regards,

Rob Joosten.

2007/10/24, [Nicolas.ROSSIGNOL@ec.europa.eu](mailto:Nicolas.ROSSIGNOL@ec.europa.eu) <[Nicolas.ROSSIGNOL@ec.europa.eu](mailto:Nicolas.ROSSIGNOL@ec.europa.eu)>:

Dear colleague,

For your information, DG Enterprise and Industry of the European Commission will launch tomorrow a Public Consultation on the 'comitology' part of the revision of the Variations Regulations. The draft legal proposal and the accompanying Consultation paper are attached to this email; they will be posted tomorrow on our website: <http://ec.europa.eu/enterprise/pharmaceuticals/varreg/index.htm>

<<draftRegulation-NR-2007-10-24.pdf>> <<Consultation paper-NR-2007-10-24.pdf>>

This public consultation only addresses the 'comitology' part of this Better Regulation initiative. It does not address the aspects of the review which require 'co-decision', as these aspects have already been addressed in a previous round of consultation.

Comments on this public consultation should be sent by e-mail to [nicolas.rossignol@ec.europa.eu](mailto:nicolas.rossignol@ec.europa.eu) before Friday 4 January 2008.

Yours sincerely,

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