From: [redacted] (GROW)
Sent: 25 September 2017 14:32
To: [redacted]'
Cc: [redacted] (ENV); [redacted] (GROW)
Subject: RE: Daikin-AstraZeneca meeting 26/09 - Stockholm Convention and REACH PFOA Restriction - Questions

Dear [redacted]

Thank you for your message. To give you a reply as early as possible before your meeting, I have replied below (in green) to those of your questions that fall under REACH. I'm sure [redacted] will respond shortly to the last question on thresholds and risk assessment in relation to the POP Regulation. I will not attend the meeting tomorrow but in any event my replies contain the sum of my knowledge on these issues!

I agree with your analysis of the situation. The incidental manufacture of PFOI (a PFOA-related substance) is allowed by virtue of paragraph 4(b) of the restriction in entry 68 of Annex XVII to REACH. The export of PFOI to Japan is not restricted by REACH (as "placing on the market" means placing on the market in the EU, which is deemed to include import). The use of PFOI in the manufacture of PFOB in Japan is of course also not restricted by REACH. However the import (placing on the market in the EU) of PFOB, containing PFOI in a concentration above 1000ppb, would contravene paragraph 2(a) of the restriction after 4 July 2020.

Questions:

- Can a review of the REACH PFOA Restriction be envisaged in order to include a derogation for the use of PFOB in the production of pharmaceuticals, in case the inclusion of PFOA and PFOA-related substances in the Stockholm Convention and subsequently in the EU POP Regulation does not take place in 2020 as currently foreseen but is postponed? Based on the Stockholm Convention decision-making cycle, any postponement would be of at least two years.
  Article 69(5) of REACH provides that either a Member State or the European Chemicals Agency may propose the re-examination of an existing restriction and that a decision whether to do so must be taken in accordance with the examination comitology procedure. In practice, if it is the Commission/the Agency that proposes re-examination this step is dispensed with.
- Would a revision of the REACH PFOA restriction follow the same process as the adoption of a new restriction (preparation of an Annex XV dossier, assessment by RAC and SEAC) and how long would the revision process take? At least two years?
  The Commission could ask the Executive Director of the Agency to request the RAC and SEAC Committees to prepare an opinion on a possible exemption. This could take several months and then the Commission would prepare a proposal which would have to undergo inter-services consultation and then be discussed and voted on in the REACH Committee. The usual scrutiny period in Council and Parliament under the regulatory procedure with scrutiny would apply. Your estimate of around two years for the whole process seems about right.
- How could Daikin and AstraZeneca support the process?
  The Agency's committees will organize public consultation to which both companies could contribute. Details regarding volume of production, socio-economic effects etc. would of course be helpful.
- Would a derogation for the use of PFOB for the purpose of producing pharmaceuticals be a good first basis for a derogation request?

Any derogation should probably take the form of an exemption for the placing on the market of substances that contain PFOA-related substances and that are intended exclusively for use in the production of pharmaceutical products.

- Can the thresholds which are currently included in the REACH PFOA Restriction be lowered in the EU POP Regulation? Would that require another risk assessment under the EU POP Regulation? DG ENV to reply separately

Kind regards,

[redacted]

European Commission
DG for Internal Market, Industry, Entrepreneurship and SMEs
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From: [redacted]@kreab.com]
Sent: Sunday, September 24, 2017 4:31 PM
To: [redacted] (GROW)
Cc: [redacted] ENV)
Subject: Daikin-AstraZeneca meeting 26/09 - Stockholm Convention and REACH PFOA Restriction - Questions

Dear [redacted],

I'm writing to you regarding the meeting with Daikin, producer of fluorochemistry, and AstraZeneca, producer of pharmaceuticals, next Tuesday 26 September, to discuss a derogation request under the Stockholm Convention for PFOI, a PFOA-related substance. Please find below a description of the case and the questions we would be grateful to clarify with you with respect to the REACH PFOA Restriction.

Background:
PFOI, a PFOA related substance, occurs as unavoidable byproduct from the production of C6/short-chain fluorinated substances.
Daikin reprocesses a fraction of PFOI into another substance called PFOB. This process takes place in Japan. PFOB is then exported to different countries (including in the EU) to be used by AstraZeneca in the production of certain pharmaceuticals for lung/respiratory diseases. All stages of the process take place under strict conditions of control and there is at present no

alternatives neither to PFOI to produce PFOB, nor to PFOB to produce pharmaceuticals with equivalent performance.

Daikin and AstraZeneca have been advocating for a derogation for this use in the context of the discussions on the inclusion of PFOA and PFOA-related substances in the Stockholm Convention. This derogation request has been included in the *draft Risk Management Evaluation report* on PFOA and PFOA-related substances (para 216 (k)), *attached*) and will be discussed at the next POPRC in October.

The issue from an EU perspective is that PFOB, which has started to be imported in the EU for the production of pharmaceuticals, contains PFOI above the REACH PFOA Restriction threshold of 1 ppm. Only PFOB raises a concern in terms of threshold (the PFOI level in the pharmaceutical products is of a few ppb, so far from 1 ppm).
There is no derogation for the use of PFOB in the production of pharmaceuticals in the REACH PFOA Restriction. Provided a derogation is included at Stockholm Convention level, it may be transposed in the EU POP Regulation (that will repeal the REACH PFOA Restriction) but this may not happen before the entry into effect of the REACH PFOA Restriction on 4 July 2020.

Questions:

- Can a review of the REACH PFOA Restriction be envisaged in order to include a derogation for the use of PFOB in the production of pharmaceuticals, in case the inclusion of PFOA and PFOA-related substances in the Stockholm Convention and subsequently in the EU POP Regulation does not take place in 2020 as currently foreseen but is postponed? Based on the Stockholm Convention decision-making cycle, any postponement would be of at least two years.
- Would a revision of the REACH PFOA restriction follow the same process as the adoption of a new restriction (preparation of an Annex XV dossier, assessment by RAC and SEAC) and how long would the revision process take? At least two years?
- How could Daikin and AstraZeneca support the process?
- Would a derogation for the use of PFOB for the purpose of producing pharmaceuticals be a good first basis for a derogation request?
- Can the thresholds which are currently included in the REACH PFOA Restriction be lowered in the EU POP Regulation? Would that require another risk assessment under the EU POP Regulation?

We hope that you will be available for the meeting and to have the opportunity to discuss further these issues with you.
Kind regards,
[redacted]

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