Strasbourg, 15/01/2018
Complaint 2111/2017/MDC

Dear [Redacted],

On 30 November 2017, acting on behalf of BEUC - The European Consumer Organisation (the complainant), you submitted a complaint to the European Ombudsman against the European Commission about the Commission’s failure to carry out a review, in 2015, of the Cosmetics Regulation with regard to substances with endocrine-disrupting properties.

I understand that your complaint is that the Commission has failed to complete the review of Regulation (EC) No 1223/20091 (the Cosmetics Regulation) with regard to substances with endocrine-disrupting properties, despite its obligation, laid down in Article 15(4) of the Cosmetics Regulation, to review the Regulation with regard to those substances “at the latest on 11 January 2015”.

In support of the complaint, you argue that:

1. The legislature set an unequivocal deadline for the Commission to review the Cosmetics Regulation, regardless of whether agreed criteria for identifying substances with endocrine-disrupting properties are available. The ongoing discussions on the scientific criteria for the definition of endocrine disruptors in the sectors of biocides and plant protection products (the ‘EDC criteria’)2, therefore, cannot justify the

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In point 3.1.1. of the minutes, it is stated that “… a draft report on the evaluation of the Cosmetics Regulation as regards endocrine disruptors … was prepared in view of its adoption by the College by the
Commission’s decision to postpone the review of the Cosmetics Regulation. In any event, it is unclear whether the EDC criteria can be applied to other sectors or product groups (besides biocides and plant protection products), such as cosmetics.

2. The Commission’s decision to postpone the review may create unnecessary risks for consumers and conflicts with the Cosmetics Regulation’s objective of ensuring a high level of protection of human health.

I understand that you would like the review envisaged by Article 15(4) of the Cosmetics Regulation to be completed without further delay.

I have contacted the Commission to receive its views. The time limit for the Commission’s reply is mid-April 2018.

I will get back to you as soon as I have more information to share with you.

If you have any questions, please feel free to contact the case handler, Ms Maria Depasquale, at the following telephone number: +33 (0)388

Yours sincerely,

Emily O’Reilly
European Ombudsman
From: BEUC - Directors Office <directorsoffice@beuc.eu>
Sent: 08 May 2018 11:21
To: Euro-Ombudsman
Cc: BEUC - Directors Office; BEUC - Safety
Subject: Reply to comments of the European Commission regarding complaint 2111/2017/MDC

Ms. Emily O’Reilly
European Ombudsman
Unit 1
avenue du Président Robert Schuman 1
CS 30403
F - 67001 Strasbourg Cedex

Ref.: BEUC-L-2018-116/cm 8 May 2018

Subject: Reply to comments of the European Commission regarding complaint 2111/2017/MDC

Dear Ms. O’Reilly,

Thank you for your letter of 13 April 2018, informing us of the European Commission’s reply to our complaint about the Commission’s decision to postpone the review of the Cosmetics Regulation with regard to substances with endocrine-disrupting properties (the EDC review).

On behalf of BEUC, The European Consumer Organisation, I take this opportunity to thank you for investigating the Commission’s failure to meet its obligations under the Cosmetics Regulation. We have carefully read the Commission’s reply to our complaint and wish to make the following comments. These comments should be read in conjunction with the arguments we brought in our initial complaint of 30 November 2017.

The review obligation is unequivocal

Article 15(4) of the Cosmetics Regulation (Regulation (EC) No 1223/2009) instructs the European Commission to review the Regulation with regard to substances with endocrine-disrupting properties, when Community or internationally agreed criteria for identifying such substances are available, or at the latest on 11 January 2015.

While the Commission acknowledges the review obligation, it also maintains that the on-going discussions on scientific criteria for the identification of endocrine disruptors in the sectors of biocides and plant protection products justifies the decision to postpone the EDC review. BEUC firmly disagrees with this view.

As we observe in our complaint, the specific formulation of the Cosmetics Regulation’s Article 15(4) as well as the absence of a legal reference to either the Plant Protection Products Regulation or the Biocidal Product Regulation
demonstrate that the EDC review obligation exists in its own right and independent of the Commission’s obligation to develop EDC criteria in other sectors.

We further observe that the Legislator enacted the Cosmetics Regulation shortly after the Plant Protection Products Regulation (in October and November 2009, respectively). Whereas the Plant Protection Products Regulation obliges the Commission to develop EDC criteria by 14 December 2013 (cf. Annex II, point 3.6.5), the Legislator included no reference to this obligation in the Cosmetics Regulation. Article 15(4) of the Cosmetics Regulation, and the Travaux Préparatoires, instead plainly demonstrates the Legislator’s intention that the Commission shall complete the EDC review no later than 5 years after the date of entry into force of the Regulation, that is 11 January 2015.

BEUC therefore reiterates that the on-going discussions on EDC criteria in the sectors of biocides and plant protection products in no way can justify the Commission’s decision to postpone the review of the Cosmetics Regulation.

The Commission’s explanation ignores the Judgment in Case T-521/14 Sweden v Commission

The Commission argues that “[at] the date of 11 January 2015 laid down in the provision, the ‘Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties’ were not yet available. Indeed, the Commission had been working on the determination of criteria to identify endocrine disruptors (ED), with a focus on biocides and plant protection products, for some years. The Commission carried out a comprehensive impact assessment to analyse different options for defining the criteria for the identification of endocrine disruptors. […] cosmetics were considered in the broader context of this work and due to the ongoing impact assessment, it was decided that ensuring coherence throughout the sectors was important, without creating unnecessary risk for consumers and without lowering the level of protection of human health.” (our emphasis)

This explanation however ignores the judgment by the General Court of the European Union in Case T-521/14 Sweden v Commission[1] that: “With regard to the alleged necessity, referred to by the Commission, of carrying out an impact analysis with a view to evaluating the effects of the various possible solutions, the General Court finds that that there is no provision of the [Biocidal Products Regulation] which requires such an impact analysis. What is more, even if the Commission ought to have carried out such an impact analysis, that does not in any way exonerate it, in the absence of provisions to that effect, from complying with the deadline set for the adoption of those delegated acts. (our emphasis)

“The General Court therefore concludes that, by failing to adopt delegated acts as regards the specification of the scientific criteria for the determination of endocrine-disrupting properties, the Commission has failed to fulfil its obligations under Regulation No 528/2012.”

By extension, and absent provisions in the Cosmetics Regulation requiring an impact analysis, the alleged need to ensure coherence with other sectors does not legitimize the Commission’s failure to complete the EDC review by 11 January 2015.

The Commission’s explanation is inconsistent

As we explain in our complaint, the EDC criteria proposed by the Commission are developed exclusively based on a sectoral view (biocides/pesticides). It is therefore unclear if the proposed criteria can be applied to other sectors or product groups, such as cosmetics.

Indeed, according to the summary records[2] of the Standing Committee on Plants, Animals, Food and Feed and the Expert Group for Biocidal Products between June 2016 and July 2017, the Commission repeatedly acknowledged that the EDC criteria are not directly applicable to other sectors, including cosmetics.

At the 69th meeting of the Expert Group for Biocidal Products,[3] held on 28 February 2017, the Commission thus “re-iterated that the criteria are not intended to be directly applicable to other sectors. However, they are drafted in a way that they can be transposed to other sectors. Some adaptation before application to other sectors may be foreseen if needed.” Likewise, at the 73rd meeting of the Expert Group for Biocidal Products,[4] held on 12 July 2017, the Commission “pointed out that the criteria proposed in the Delegated Regulation are intended solely for the
specific legal context of that Regulation – the forthcoming strategy [on Endocrine Disruptors] will be the occasion to clarify how the criteria would be incorporated in other legal frameworks [...] .”

However, if as the Commission maintains the EDC criteria apply exclusively to the sectors of pesticides and biocides, then the Commission had no reason to await the conclusion of the ongoing discussions over such criteria since they could not be expected to impact the conduct or outcome of the EDC review. The Commission’s explanation for the delayed EDC review would thus in short seem inconsistent with the approach taken to the development of EDC criteria.

**Procedural implications of the delayed EDC review**

The Commission notes that “Article 15(4) of the Cosmetics Regulation does not require the Commission to adopt a legal act (such as a Regulation or a legislative proposal) with a defined content.” BEUC acknowledges that unlike for example Article 5(3) of the Biocidal Products Regulation, the Commission is not obliged to revise but instead to review the Cosmetics Regulation with regard to substances with endocrine disrupting properties.

We are however concerned about the procedural implications of the delayed EDC review. If the EDC review were to establish the need for amendments to the Cosmetics Regulation to ensure a high level of consumer protection, the Commission would be unable to conclude the legislative procedure required to achieve such amendments within its current mandate.

A new European Parliament will be elected in May 2019, while a new college of Commissioner will enter office during the second half of 2019. This change in legislature will inevitably further postpone a political decision on a possible revision of the Cosmetics Regulation with regard to cosmetic ingredients with endocrine disrupting properties. This delay could have been avoided had the Commission respected the deadline set out in Article 15(4) of the Cosmetics Regulation.

BEUC therefore considers that the Commission’s failure to expediently complete the EDC review constitutes maladministration. We are further concerned that the decision to postpone the EDC review towards the end of the current Commission’s mandate could prejudge the review’s conclusions and recommendations.

**Conclusion**

Considering the above, BEUC maintains that the on-going discussions on EDC criteria in the sectors of biocides and plant protection products can in no way justify the Commission’s decision to postpone the review of the Cosmetics Regulation. We further consider that the unlawful failure to complete the EDC review may create unnecessary risks for consumers.

The European Commission must complete the review foreseen in Article 15(4) of the Cosmetics Regulation without further delay, and independent of the discussions on EDC criteria in the sectors of biocides and plant protection products. It is in this context imperative that the EDC review provides a sufficient basis to allow a new college of Commissioners to swiftly take a political decision on how to ensure a high level of consumer protection against cosmetic ingredients with endocrine-disrupting properties, including, where appropriate, through a revision of the Cosmetics Regulation.

We thank you in advance and remain at your disposal should you need any further information.

Your sincerely,
Subject: Reply to comments of the European Commission regarding complaint 2111/2017/MDC

Dear Ms. O’Reilly,

Thank you for your letter of 13 April 2018, informing us of the European Commission’s reply to our complaint about the Commission’s decision to postpone the review of the Cosmetics Regulation with regard to substances with endocrine-disrupting properties (the EDC review).

On behalf of BEUC, The European Consumer Organisation, I take this opportunity to thank you for investigating the Commission’s failure to meet its obligations under the Cosmetics Regulation. We have carefully read the Commission’s reply to our complaint and wish to make the following comments. These comments should be read in conjunction with the arguments we brought in our initial complaint of 30 November 2017.

The review obligation is unequivocal
Article 15(4) of the Cosmetics Regulation (Regulation (EC) No 1223/2009) instructs the European Commission to review the Regulation with regard to substances with endocrine-disrupting properties, when Community or internationally agreed criteria for identifying such substances are available, or at the latest on 11 January 2015.

While the Commission acknowledges the review obligation, it also maintains that the on-going discussions on scientific criteria for the identification of endocrine disruptors in the sectors of biocides and plant protection products justifies the decision to postpone the EDC review. BEUC firmly disagrees with this view.

As we observe in our complaint, the specific formulation of the Cosmetics Regulation’s Article 15(4) as well as the absence of a legal reference to either the Plant Protection Products Regulation or the Biocidal Product Regulation demonstrate that the EDC review obligation exists in its own right and independent of the Commission’s obligation to develop EDC criteria in other sectors.

We further observe that the Legislator enacted the Cosmetics Regulation shortly after the Plant Protection Products Regulation (in October and November 2009, respectively). Whereas the Plant Protection Products Regulation obliges the Commission to develop EDC criteria by 14 December 2013 (cf. Annex II, point 3.6.5), the Legislator included no reference to this obligation in the Cosmetics Regulation. Article 15(4) of the Cosmetics Regulation, and the Travaux Préparatoires, instead plainly demonstrates the Legislator’s intention that the Commission shall complete the EDC review no later than 5 years after the date of entry into force of the Regulation, that is 11 January 2015.
BEUC therefore reiterates that the on-going discussions on EDC criteria in the sectors of biocides and plant protection products in no way can justify the Commission's decision to postpone the review of the Cosmetics Regulation.

**The Commission's explanation ignores the Judgment in Case T-521/14 Sweden v Commission**

The Commission argues that "[at] the date of 11 January 2015 laid down in the provision, the 'Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties' were not yet available. Indeed, the Commission had been working on the determination of criteria to identify endocrine disruptors (ED), with a focus on biocides and plant protection products, for some years. The Commission carried out a comprehensive impact assessment to analyse different options for defining the criteria for the identification of endocrine disruptors. [...] cosmetics were considered in the broader context of this work and due to the ongoing impact assessment, it was decided that ensuring coherence throughout the sectors was important, without creating unnecessary risk for consumers and without lowering the level of protection of human health." *(our emphasis)*

This explanation however ignores the judgment by the General Court of the European Union in Case T-521/14 Sweden v Commission*¹ that: "With regard to the alleged necessity, referred to by the Commission, of carrying out an impact analysis with a view to evaluating the effects of the various possible solutions, the General Court finds that that there is no provision of the [Biocidal Products Regulation] which requires such an impact analysis. What is more, even if the Commission ought to have carried out such an impact analysis, that does not in any way exonerate it, in the absence of provisions to that effect, from complying with the deadline set for the adoption of those delegated acts. *(our emphasis)*

"The General Court therefore concludes that, by failing to adopt delegated acts as regards the specification of the scientific criteria for the determination of endocrine-disrupting properties, the Commission has failed to fulfil its obligations under Regulation No 528/2012."

By extension, and absent provisions in the Cosmetics Regulation requiring an impact analysis, the alleged need to ensure coherence with other sectors does not legitimize the Commission's failure to complete the EDC review by 11 January 2015.

**The Commission's explanation is inconsistent**

As we explain in our complaint, the EDC criteria proposed by the Commission are developed exclusively based on a sectoral view (biocides/pesticides). It is therefore unclear if the proposed criteria can be applied to other sectors or product groups, such as cosmetics.

Indeed, according to the summary records*¹ of the Standing Committee on Plants, Animals, Food and Feed and the Expert Group for Biocidal Products between June 2016 and July 2017, the Commission repeatedly acknowledged that the EDC criteria are not directly applicable to other sectors, including cosmetics.

At the 69th meeting of the Expert Group for Biocidal Products,*¹ held on 28 February 2017, the Commission thus "re-iterated that the criteria are not intended to be directly applicable to other sectors. However, they are drafted in a way that they can be transposed to other sectors. Some adaptation before application to other sectors may be foreseen if needed." Likewise, at the 73rd meeting of the Expert Group for Biocidal Products,*¹ held on 12 July 2017, the Commission "pointed out that the criteria proposed in the Delegated Regulation are intended solely for the specific legal context of that Regulation – the forthcoming strategy [on Endocrine Disruptors] will be the occasion to clarify how the criteria would be incorporated in other legal frameworks [...]."
However, if as the Commission maintains the EDC criteria apply exclusively to the sectors of pesticides and biocides, then the Commission had no reason to await the conclusion of the ongoing discussions over such criteria since they could not be expected to impact the conduct or outcome of the EDC review. The Commission’s explanation for the delayed EDC review would thus in short seem inconsistent with the approach taken to the development of EDC criteria.

Procedural implications of the delayed EDC review
The Commission notes that “Article 15(4) of the Cosmetics Regulation does not require the Commission to adopt a legal act (such as a Regulation or a legislative proposal) with a defined content.” BEUC acknowledges that unlike for example Article 5(3) of the Biocidal Products Regulation, the Commission is not obliged to revise but instead to review the Cosmetics Regulation with regard to substances with endocrine disrupting properties.

We are however concerned about the procedural implications of the delayed EDC review. If the EDC review were to establish the need for amendments to the Cosmetics Regulation to ensure a high level of consumer protection, the Commission would be unable to conclude the legislative procedure required to achieve such amendments within its current mandate.

A new European Parliament will be elected in May 2019, while a new college of Commissioner will enter office during the second half of 2019. This change in legislature will inevitably further postpone a political decision on a possible revision of the Cosmetics Regulation with regard to cosmetic ingredients with endocrine disrupting properties. This delay could have been avoided had the Commission respected the deadline set out in Article 15(4) of the Cosmetics Regulation.

BEUC therefore considers that the Commission’s failure to expediently complete the EDC review constitutes maladministration. We are further concerned that the decision to postpone the EDC review towards the end of the current Commission’s mandate could prejudice the review’s conclusions and recommendations.

Conclusion
Considering the above, BEUC maintains that the on-going discussions on EDC criteria in the sectors of biocides and plant protection products can in no way justify the Commission’s decision to postpone the review of the Cosmetics Regulation. We further consider that the unlawful failure to complete the EDC review may create unnecessary risks for consumers.

The European Commission must complete the review foreseen in Article 15(4) of the Cosmetics Regulation without further delay, and independent of the discussions on EDC criteria in the sectors of biocides and plant protection products. It is in this context imperative that the EDC review provides a sufficient basis to allow a new college of Commissioners to swiftly take a political decision on how to ensure a high level of consumer protection against cosmetic ingredients with endocrine-disrupting properties, including, where appropriate, through a revision of the Cosmetics Regulation.

We thank you in advance and remain at your disposal should you need any further information.

Your sincerely,

[Signature]

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ii Available at: https://ec.europa.eu/health/endocrine_disruptors/events_en#anchor

iii Available at: https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/ev_20170226_ml_en.pdf

Strasbourg, 13/04/2018

Complaint 2111/2017/MDC

Subject: Request for comments

Dear [Name],

I am sending you, for your information, a copy of the reply to your complaint which we have now received from the European Commission.

If you wish to make any comments on the Commission's reply, please send them to me within one month of the date of this letter.

If you decide not to send any comments, I will base my decision on the information you have already provided, and on the Commission's reply.

Yours sincerely,

Emily O'Reilly
European Ombudsman

Enclosure: Copy of the reply from the European Commission
REPLY_201702111_20180327_171639
Your complaint has been submitted to the European Ombudsman. We will send you an acknowledgement of receipt within a few days.

NB - Please note that this e-mail was sent from a notification only e-mail address. If you wish to contact technical support, please use the link below:

Contact technical support

Sender

From: safety@beuc.eu
Date: Thursday, November 30, 2017 11:15:09 AM CET

Complaint about maladministration

Part 1 - Contact information

First name: 
Surname: 
On behalf of (if applicable): BEUC - The European Consumer Organisation
Address line 1: Rue d'Arlon 80
Address line 2: 
Town/City: Brussels
County/State/Province: 
Postcode: 1040
Country: Belgium
Tel.: 
Fax: 
E-mail address: safety@beuc.eu

Part 2 - Against which European Union (EU) institution or body do you wish to complain?

European Commission

Part 3 - What is the decision or matter about which you complain? When did you become aware of it? Add annexes if necessary.

Article 15(4) of the Cosmetics Regulation (Regulation (EC) No 1223/2009) instructs the European Commission to review the Regulation with regard to substances with endocrine-disrupting properties, when Community or
internationally agreed criteria for identifying such substances are available, or at the latest on 11 January 2015. (Herein the ‘EDC review’) Despite this unambiguous deadline, the Commission has to date failed to complete the EDC review.

Since January 2015, BEUC has repeatedly raised concern about the delayed EDC review which may create unnecessary health risks for consumers. Sufficient evidence [1] links endocrine-disrupting chemicals (EDCs) to a range of severe diseases and disorders, including infertility and cancer. Cosmetics ingredients with endocrine-disrupting properties represent a significant, potential source of cumulative consumer exposure to EDCs – a fact compelling demonstrated [2] by EU consumer organisations. Consumers are in frequent, intimate and often prolonged contact with cosmetic and personal care products: a survey [3] of more than 2,300 people found that the average adult uses nine personal care products each day. This aggregate figure however hides significant variations. One in four women for example use at least 15 products daily, according to the same survey.

Cosmetic and personal care products are thus major direct sources of consumer exposure to potential EDCs, including for vulnerable groups, such as pregnant and breast-feeding women, children and persons with compromised immune responses. The failure to complete the EDC review may therefore endanger the health of millions of consumers across the EU.


Part 4 - What do you consider that the EU institution or body has done wrong?

Despite the legal deadline established by the Cosmetics Regulation, the European Commission continues to delay completion of the EDC review.

According to the 2016 Commission communication on endocrine disruptors (COM(2016) 350 final) [1], “[…] the Commission has to ‘review [the Cosmetics Regulation] with regard to substances with endocrine-disrupting properties’. This review is overdue. A screening exercise of certain cosmetic ingredients that has been contracted by the Commission is close to completion. The Commission will present the review by the end of the year.” (Our emphasis.) On 8 July 2016, Commissioner Elżbieta Bieńkowska assured [2] the European Parliament that “before end-2016, the Commission will complete the review and communicate the results.” This has not happened.

At the meeting of the Working Group on Cosmetic Products on 14 March 2017, the Commission instead informed [3] members of the Working Group that “[…] a draft report on the evaluation of the Cosmetics Regulation as regards endocrine disruptors was prepared in view of its adoption by the College by the end of 2016. However, the Commission is still examining the draft report and its adoption was postponed in light of the on-going discussions on the scientific criteria for the definition of endocrine disruptors in the sectors of biocides and plant protection products.” (Our emphasis.)

BEUC considers that the on-going discussions on the Commission’s proposed scientific criteria to determine endocrine-disrupting properties in the sectors of biocides and plant protection products (Herein the ‘EDC criteria’) do not justify the Commission’s decision to postpone the EDC review.

Under the Biocidal Product Regulation (Regulation (EC) No 528/2012) and the Plant Protection Products Regulation (Regulation (EC) No 1107/2009), the European Parliament and Council set December 2013 as a deadline for the Commission to adopt EDC criteria. The Biocidal Products Regulation in particular provides that, by 13 December 2013 at the latest, the Commission was to adopt delegated acts setting out EDC criteria. The Commission’s failure to adopt such criteria under the Biocidal Products Regulation is unlawful as established by the General Court of the European Union in December 2015.

That fact however does not exonerate the Commission from the obligation to review the Cosmetics Regulation with regard to substances with endocrine-disrupting properties. On the contrary. The specific formulation of the Cosmetics Regulation’s Article 15(4) as well as the absence of a legal reference to either the Plant Protection Products Regulation or the Biocidal Product Regulation demonstrate that the EDC review obligation exists in its own right and independent of the Commission’s obligation to develop EDC criteria in other sectors. This conclusion is further corroborated by the Travaux Préparatoires for the Cosmetics Regulation which states the legislator’s intention that the Commission shall complete the EDC review no later than 5 years after the date of entry into force of the Regulation.
Further, the EDC criteria proposed by the Commission are developed exclusively based on a sectoral view (biocides/pesticides). It is therefore unclear if the proposed criteria can be applied to other sectors or product groups, such as cosmetics. The Dutch National Institute for Public Health and the Environment (RIVM) for example concludes [4]: “Due to the ban on animal testing for cosmetic ingredients effective since 2013, it is not possible to identify a chemical as an EDC based on the draft EU criteria. If a chemical is only used in cosmetic products, it will be extremely difficult to differentiate between a potential EDC and EDC.”

Cosmetic products are a significant, direct sources of consumer exposure to potential EDCs, including for vulnerable groups, such as pregnant and breast-feeding women, children and persons with compromised immune responses. Cosmetics ingredients with endocrine-disrupting properties should therefore be regulated consistent with substances of equivalent concern, such as those that cause cancer, change DNA or are toxic to reproduction (CMRs). The Cosmetics Regulation prohibits use of known, presumed and suspected CMR substances, and a parallel approach is needed for substances with endocrine-disrupting properties to achieve a high level of consumer protection. The proposed EDC criteria however only allows for the identification of known and presumed EDCs, but excludes suspected (potential) EDCs.

This suggests that to achieve the objectives of the Cosmetics Regulation, specifically a high level of protection, the proposed EDC criteria will most certainly need to be modified and further developed. As such, and since the Commission has set aside the commitment under the 7th Environmental Action Programme to develop horizontal EDC criteria, the delay with respect to adopting the EDC criteria developed for the biocides and pesticides sectors cannot justify the failure to complete the EDC review for cosmetic products.

In short, the legislator set an unequivocal deadline for the Commission to review the Cosmetics Regulation – whether agreed criteria for identifying substances with endocrine-disrupting properties are available or not. The on-going discussions on such criteria in the sectors of biocides and plant protection products, therefore, can in no way justify the Commission’s decision to postpone the review of the Cosmetics Regulation.

BEUC further considers that the failure to review the Cosmetics Regulation with regard to substances with endocrine-disrupting properties may create unnecessary risks for consumers. The Commission’s decision to postpone the EDC review directly conflicts with the high level of protection sought by the legislator. Political concerns rather than legitimate scientific or technical reasons would thus appear to dictate the delay in completing the EDC review.


Part 5 - What, in your view, should the institution or body do to put things right?

The European Commission must complete the review foreseen in Article 15(4) of the Cosmetics Regulation without further delay, and independent of the on-going discussions on EDC criteria in the sectors of biocides and plant protection products. Based on the review, the Commission should, where appropriate, propose amendments to the Cosmetics Regulation to ensure a high level of consumer protection against substances with endocrine-disrupting properties.

Part 6 - Have you already contacted the EU institution or body concerned in order to obtain redress?

Yes (please specify and submit copies of the relevant correspondence)

On 2 February 2016, BEUC wrote [1] to Commissioner Vytenis Andriukaitis to emphasise, among others, the Commission’s failure to perform the EDC review despite the legal obligation to do so no later than 11 January 2015. Commissioner Andriukaitis’ written response dated 13 February 2016 did not address the delayed EDC review.

BEUC again raised the EDC review with the responsible Commission services at a meeting on 3 March 2017. At our request, the delayed EDC review was likewise included on the agenda for the 3 July 2017 meeting of the Working Group on Cosmetic Products.
At the July meeting, the Commission explained that the situation with regard to the EDC review was similar to the situation presented [2] at the March 2017 meeting. The Commission reiterated that the adoption of the draft EDC review report by the College had been postponed in light of the on-going discussions on the EDC criteria in the biocides and plant protection products sectors. The Commission could not provide further information about when the EDC review would be finalised.


Part 7 - If the complaint concerns work relationships with the EU institutions and bodies: have you used all the possibilities for internal administrative requests and complaints provided for in the Staff Regulations? If so, have the time limits for replies by the institutions already expired?

Not applicable

Part 8 - Has the object of your complaint already been settled by a court or is it pending before a court?

No

Part 9 - Please confirm that you have read the information below

You have read the information note on data processing and confidentiality

Part 10 - Do you agree that your complaint may be passed on to another institution or body (European or national), if the European Ombudsman decides that he is not entitled to deal with it?

Yes
Ref.: BEUC-X-2016-011/cm

2 February 2016

RE: The European Commission’s approach to chemicals which can disturb the hormonal system

Dear Commissioner Andriukaitis,

On behalf of BEUC, The European Consumer Organisation, I write to urge you to take immediate action to ensure better protection of consumers against hormone-disrupting chemicals.

Under EU biocides, pesticides and cosmetics laws, the European Commission is obliged to adopt scientific criteria identifying hormone-disrupting chemicals. So far, all legal deadlines have passed without the Commission taking action.

This failure to act is of major concern as it is impossible to restrict or ban the most harmful of these chemicals without such legal criteria. As a consequence, consumers continue to be exposed to chemicals which put our health at risk.

The General Court of the European Union has found that this failure to adopt scientific criteria is unlawful. The Court ruled that an impact assessment is not required as a precondition for setting criteria and that the Commission is obliged to keep the deadlines unambiguously set in legislation.

We were therefore disappointed to learn that the Commission nonetheless plans to continue with its impact assessment rather than swiftly adopt legal criteria. Given the Commission’s role as the Guardian of the Treaties, this disregard for the Court’s decision is alarming. Disrespecting the Court’s ruling and the need to protect consumers’ health risks alienating citizens from EU-decision making bodies.

Impact assessments should be used to improve, not threaten or delay much needed regulatory action. In view of the significant delay caused by the impact assessment for scientific criteria, BEUC calls on the Commission to review more generally the extent to which your services the Commission’s use of impact assessments is causing unnecessary delays in protecting European consumers. If this is the case, I urge the Commission to launch a wider overhaul of the Commission’s ‘Better Regulation’ agenda.

Given the public interest in the matter BEUC will make this letter publicly available.

Yours sincerely,

[Encl.: Annex – BEUC’s position on Endocrine-Disrupting Chemicals.

Annex – BEUC’s position on Endocrine-Disrupting Chemicals

Endocrine disruptors are detrimental to health and the environment
Scientists warn that exposure to endocrine-disrupting chemicals (EDCs) may cause a range of chronic and severe diseases such as obesity, cardiovascular diseases, cancer, diabetes and infertility. In September 2015, the Endocrine Society\(^2\) published its Second Scientific Statement on Endocrine-Disrupting Chemicals\(^3\) concluding that there is no longer any doubt that exposure to endocrine disruptors are contributing to some chronic endocrine-related diseases. The Endocrine Society statement includes a review of 1,300 studies on EDCs, which show more evidence than ever of the links between EDCs and health problems including: obesity and diabetes, female reproduction, male reproduction, hormone-sensitive cancers in females, prostate cancer, thyroid, and [disruption of] neurodevelopment and neuroendocrine systems.

The cost to European societies of EDC exposure is staggering.
In the EU, the cost of this exposure has recently been estimated at euros 157 billion or 1.23 percent of gross domestic product – per year.\(^4\) This estimate includes direct costs such as hospital stays, physicians' services, nursing-home care and other medical costs as well as indirect costs resulting from lost worker productivity, early death and disability, and loss of intellectual abilities caused by prenatal exposure. However, this estimate does not cover intangible cost such as a loss of life-quality, suggesting that the true cost of EDC exposure is much higher.

Consumer exposure to EDCs is ubiquitous
Given that suspected endocrine disruptors are found in many everyday products, the exposure of consumers to these harmful chemicals are of major concern for consumer health and safety. The comparative product tests undertaken by BEUC's members frequently detect endocrine disruptors in products consumers come in very close, regular and prolonged contact with, such as e.g. textiles, shoes, toys, cosmetics, bed mattresses, breast feeding pillows, play mats for children, etc. However, our members also find that endocrine disruptors are present in some but not in all products. As these toxics chemicals very often are not necessary for production – and as price often does not seem to be a decisive factor either – much of the exposure could be avoided.

The European Commission must act now to curb the threat from EDCs
On December 16, 2015 the General Court ruled that the European Commission has violated EU law by failing to adopt measures concerning the specification of scientific criteria for the determination of endocrine-disrupting properties according to Regulation No 528/2012 concerning the placing on the market and use of biocidal products.\(^5\)

The Court concluded that **criteria for the determination of endocrine-disrupting properties shall be based on science relating to the endocrine system only and not on economic considerations.** The Court further found that the impact assessment carried out by the Commission does not exonerate the Commission from complying with the deadline set in Regulation No 528/2012.

BEUC has in the past argued that the Commission's decision to carry out an impact assessment in relation to the adoption of the scientific criteria is inappropriate and we urged the Commission to promptly publish criteria which takes into account the latest scientific evidence on endocrine disrupters. This view is also shared by the EDC-Free Europe coalition which brings together over 60 health, environmental and consumer groups, campaigning to reduce exposure from endocrine-disrupting chemicals.\(^6\)

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\(^2\) The Endocrine Society is the world’s oldest, largest and most active organisation devoted to research on hormones and the clinical practice of endocrinology.


\(^4\) [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4399291/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4399291/)


\(^6\) [http://www.edc-free-europe.org/](http://www.edc-free-europe.org/)
BEUC welcomes the Court’s landmark decision as a victory for European consumers. Our everyday exposure to hormone disrupting chemicals – in our homes, workplaces and communities – must stop in order to protect the health of current and future generations.

BEUC again urges the Commission to urgently adopt criteria which clearly identify all EDCs. In particular, BEUC calls on the Commission to adopt EDC criteria in accordance with ‘option 3’ outlined in the roadmap on ‘Defining criteria for identifying Endocrine Disruptors’ as this will enable the EU to effectively address the threats of long-term health and environmental damage posed by EDCs. Adopting EDC criteria is for example a precondition for reviewing the Cosmetics Regulation with regard to substances with endocrine-disrupting properties – a review the Commission has failed to perform despite an obligation to do so no later than 11 January 2015. Until such criteria are adopted, the EU should apply the precautionary principle and ban the use of EDCs in consumer goods where safer alternatives are available.

END

Dear [Name],

Thank you for your suggestions.

Both topics will appear on the revised draft agenda which will be posted shortly on CIRCABC.

Best regards,

[Name]  
Legal Officer

European Commission  
DG for Internal Market, Industry, Entrepreneurship and SMEs  
Unit D4/ Health Technology and Cosmetics

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Our Websites: ec.europa.eu/growth

Dear [Name],

Thank you for your email.

Looking over the draft agenda, we note that ‘an update on Formaldehyde’ is not foreseen. Considering that the legal deadline for amending the Annexes to the Cosmetics Regulation expired on 1 April 2017, we are somewhat surprised to not see this item included in the agenda. BEUC would therefore appreciate if the Commission could clarify the current legal status of this substance and products containing it as well as what concrete measures the Commission intends to take in light of the 1 April 2017 deadline.
Further, in light of the ongoing delay in adopting criteria to identify endocrine-disrupting properties under the Biocidal Products Regulation, we would appreciate if the Commission could clarify the timeline for concluding the review of the Cosmetics Regulation with regard to Endocrine Disruptors foreseen in article 15(4), including what concrete steps the Commission intends to undertake before concluding the review. Does the Commission for example intend to create an opportunity for stakeholders to give input to the review in line with the commitments set out in the Commission’s Better Regulation agenda? We would also appreciate if the Commission would share its assessment of whether the EDC criteria as currently proposed under the Biocidal Product Regulation could be applied to cosmetics products or if special allowance would be required to achieve the level of consumer protection desired by the Legislator?

Thank you in advance.

Kind regards,

[Signature]

Project Officer on Chemicals and International Trade Agreements

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B-1040 Brussels
Tel. +32(0)2 [redacted]
Mob. [redacted]

www.beuc.eu

---

From: DIGIT-CIRCABC@nomail.ec.europa.eu [mailto:DIGIT-CIRCABC@nomail.ec.europa.eu]
Sent: 01 June 2017 13:13
To: [redacted]
Subject: Draft Agenda - AoB

Dear Members of the Working Group on Cosmetic Products,

The Draft Agenda of the WG meeting on 3 July 2017 has been shared via CIRCABC.

We would be grateful if you could communicate to us in writing any issues you would like to discuss under 'Any Other Business'.
Please send us your requests by Friday, 16 June 2017 at the latest by sending an email to:

Best regards,

Please consider the environment before deciding to print this e-mail.

This e-mail has been sent by the CIRCABC application. If you have any question, feel free to use the contact form of CIRCABC.

This e-mail and any attachments thereto may contain information which is confidential and/or protected by intellectual property rights and are intended for the sole use of the recipient(s) named above. Any use of the information contained herein (including, but not limited to, total or partial reproduction, communication or distribution in any form) by persons other than the designated recipient(s) is prohibited. Thank you for your cooperation.
Strasbourg, 07/02/2019

Complaint 2111/2017/MDC

Decision of the European Ombudsman in the above case on the time taken by the European Commission to review the Cosmetics Regulation with regard to substances with endocrine-disrupting properties

Dear Mr President,

Please find enclosed a copy of my above decision, which has been sent to the complainant, BEUC - The European Consumer Organisation.

On the basis of my inquiry into this complaint, I have decided to close it with the following conclusions:

As the Commission has now presented its review of the Cosmetics Regulation with regard to substances with endocrine disrupting properties, no further inquiries into the complaint are justified. Given that the purpose of the review is to ensure that public health and the environment are protected, the Ombudsman regrets that the Commission completed this review, almost two years after the deadline to which it had publicly committed.

The Commission should inform the Ombudsman as soon as it has drawn up the priority list mentioned in its review and, within one year, on the further steps that have been completed in this area.
Yours sincerely,

Emily O'Reilly
European Ombudsman

Enclosure:
• Decision on complaint 2111/2017/MDC
Strasbourg, 07/02/2019
Complaint 2111/2017/MDC

Subject: Decision of the European Ombudsman in the above case on the time taken by the European Commission to review the Cosmetics Regulation with regard to substances with endocrine-disrupting properties

Dear [Name]

Acting on behalf of BEUC - The European Consumer Organisation, you submitted a complaint to the European Ombudsman against the European Commission concerning the above issue.

After a careful analysis of all the information submitted to me, I have decided to close my inquiry with the following conclusions:

As the Commission has now presented its review of the Cosmetics Regulation with regard to substances with endocrine disrupting properties, no further inquiries into the complaint are justified. Given that the purpose of the review is to ensure that public health and the environment are protected, the Ombudsman regrets that the Commission completed this review, almost two years after the deadline to which it had publicly committed.

The Commission should inform the Ombudsman as soon as it has drawn up the priority list mentioned in its review and, within one year, on the further steps that have been completed in this area.

Please find enclosed my decision on your complaint.
Yours sincerely,

Emily O'Reilly
European Ombudsman

Enclosure: Decision on complaint 2111/2017/MDC
Dear Koen,

Thanks again for interesting talk just now – it was a pleasure meeting you and Fergal! Please also convey my warmest greetings to Rosita!

I am especially happy to have met you since I meant to follow up with your colleague, Ms Maria Depasquale regarding BEUC’s complaint over the Commission’s delay in finalizing the review of the Cosmetics Regulation with regard to endocrine disruptors (Complaint 2111/2017/MDC)

As mentioned just now, and also explain in our complaint (attached), we understand that the Commission has already finalized the review, but delays the adoption and publication of its conclusions. The latest intelligence we have from sources within the Commission is that the review report was in inter-service consultation before the summer break (in July), but that the finalization was again delayed, possibly by the College itself, as a result of disagreements among the Commission services over the Commission Communication ‘towards a more comprehensive EU framework on endocrine disruptors’. Should this be the case it again seems to confirm the concern expressed in our complaint that political and not technical/scientific considerations as claimed by the Commission explains the delayed review.

My understanding is the Communication is meant to form the ‘chapeau’ for a package on endocrine disruptors, which will also include the delayed Cosmetics review. At this stage, we have no information on the Communication’s timeline for the Communication or the review, although the Communication was initially foreseen during Q3 2018 – as you may also have seen the Communication was confirmed in the letter of intent send by President Juncker to President Tajani and Chancellor Kurz earlier this week. We hope to learn more about the timeline when we meet the Commission services responsible for coordinating the Communication next week – and will of course keep you in the loop.

In the meantime, I sincerely hope it will be possible for the EU Ombudsman to finalize her investigation before the Commission communicates the results of the EDC review (understanding of course the number of ongoing cases).

I am of course happy to answer any questions you or your colleagues might have!

Have a lovely weekend!

Best wishes,

[Redacted]
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B-1040 Brussels
Tel. +32(0)2
Mob. +32

www.beur.eu

Consult our entry in the EC register for interest representatives
Think before you print
BEUC ALERTS OMBUDSMAN ABOUT EU COMMISSION DRAGGING ITS FEET ON ENDOCRINE DISRUPTORS IN COSMETICS

Copy of complaint submitted on 30 November 2017

Contact: [REDACTED] – safety@beuc.eu
BEUC alerts Ombudsman about EU Commission dragging its feet on endocrine disruptors in cosmetics

Copy of complaint submitted on 30 November 2017

Contact info
First name: [Redacted]
Surname: [Redacted]
On behalf of: BEUC - The European Consumer Organisation
E-mail address: safety@beuc.eu

Against which European Union (EU) institution or body do you wish to complain?
The European Commission

What is the decision or matter about which you complain? When did you become aware of it?

Article 15(4) of the Cosmetics Regulation (Regulation (EC) No 1223/2009) instructs the European Commission to review the Regulation with regard to substances with endocrine-disrupting properties, when Community or internationally agreed criteria for identifying such substances are available, or at the latest on 11 January 2015. (Herein the ‘EDC review’). Despite this unambiguous deadline, the Commission has to date failed to complete the EDC review.

Since January 2015, BEUC has repeatedly raised concern about the delayed EDC review which may create unnecessary health risks for consumers. Sufficient evidence links endocrine-disrupting chemicals (EDCs) to a range of severe diseases and disorders, including infertility and cancer. Cosmetics ingredients with endocrine-disrupting properties represent a significant, potential source of cumulative consumer exposure to EDCs – a fact compelling demonstrated by EU consumer organisations. Consumers are in frequent, intimate and often prolonged contact with cosmetic and personal care products: a survey of more than 2,300 people found that the average adult uses nine personal care products each day. This aggregate figure however hides significant variations. One in four women for example use at least 15 products daily, according to the same survey.

Cosmetic and personal care products are thus major direct sources of consumer exposure to potential EDCs, including for vulnerable groups, such as pregnant and breast-feeding women, children and persons with compromised immune responses. The failure to complete the EDC review may therefore endanger the health of millions of consumers across the EU.

What do you consider that the EU institution or body has done wrong?

Despite the legal deadline established by the Cosmetics Regulation, the European Commission continues to delay completion of the EDC review.

According to the 2016 Commission communication on endocrine disruptors (COM(2016) 350 final), "[...] the Commission has to ‘review [the Cosmetics Regulation] with regard to substances with endocrine-disrupting properties’. This review is overdue. A screening exercise of certain cosmetic ingredients that has been contracted by the Commission is close to completion. The Commission will present the review by the end of the year." (Our emphasis.) On 8 July 2016, Commissioner Elżbieta Bienkowska assured the European Parliament that “before end-2016, the Commission will complete the review and communicate the results.” This has not happened.
At the meeting of the Working Group on Cosmetic Products on 14 March 2017, the Commission instead informed members of the Working Group that “[...] a draft report on the evaluation of the Cosmetics Regulation as regards endocrine disruptors was prepared in view of its adoption by the College by the end of 2016. However, the Commission is still examining the draft report and its adoption was postponed in light of the ongoing discussions on the scientific criteria for the definition of endocrine disruptors in the sectors of biocides and plant protection products.” (Our emphasis.)

BEUC considers that the on-going discussions on the Commission’s proposed scientific criteria to determine endocrine-disrupting properties in the sectors of biocides and plant protection products (Herein the ‘EDC criteria’) do not justify the Commission’s decision to postpone the EDC review.

Under the Biocidal Product Regulation (Regulation (EC) No 528/2012) and the Plant Protection Products Regulation (Regulation (EC) No 1107/2009), the European Parliament and Council set December 2013 as a deadline for the Commission to adopt EDC criteria. The Biocidal Products Regulation in particular provides that, by 13 December 2013 at the latest, the Commission was to adopt delegated acts setting out EDC criteria. The Commission’s failure to adopt such criteria under the Biocidal Products Regulation is unlawful as established by the General Court of the European Union in December 2015.

That fact however does not exonerate the Commission from the obligation to review the Cosmetics Regulation with regard to substances with endocrine-disrupting properties. On the contrary. The specific formulation of the Cosmetics Regulation's Article 15(4) as well as the absence of a legal reference to either the Plant Protection Products Regulation or the Biocidal Product Regulation demonstrate that the EDC review obligation exists in its own right and independent of the Commission’s obligation to develop EDC criteria in other sectors. This conclusion is further corroborated by the Travaux Préparatoires for the Cosmetics Regulation which states the legislator's intention that the Commission shall complete the EDC review no later than 5 years after the date of entry into force of the Regulation.

Further, the EDC criteria proposed by the Commission are developed exclusively based on a sectoral view (biocides/pesticides). It is therefore unclear if the proposed criteria can be applied to other sectors or product groups, such as cosmetics. The Dutch National Institute for Public Health and the Environment (RIVM) for example concludes: “Due to the ban on animal testing for cosmetic ingredients effective since 2013, it is not possible to identify a chemical as an EDC based on the draft EU criteria. If a chemical is only used in cosmetic products, it will be extremely difficult to differentiate between a potential EDC and EDC.”

Cosmetic products are a significant, direct sources of consumer exposure to potential EDCs, including for vulnerable groups, such as pregnant and breast-feeding women, children and persons with compromised immune responses. cosmetics ingredients with endocrine-disrupting properties should therefore be regulated consistent with substances of equivalent concern, such as those that cause cancer, change DNA or are toxic to reproduction (CMRs). The Cosmetics Regulation prohibits use of known, presumed and suspected CMR substances, and a parallel approach is needed for substances with endocrine-disrupting properties to achieve a high level of consumer protection. The proposed EDC criteria however only allows for the identification of known and presumed EDCs, but excludes suspected (potential) EDCs.

This suggests that to achieve the objectives of the Cosmetics Regulation, specifically a high level of protection, the proposed EDC criteria will most certainly need to be modified and further developed. As such, and since the Commission has set aside the commitment under the 7th Environmental Action Programme to develop horizontal EDC criteria, the delay with respect to adopting the EDC criteria developed for the biocides and pesticides sectors cannot justify the failure to complete the EDC review for cosmetics.
In short, the legislator set an unequivocal deadline for the Commission to review the Cosmetics Regulation – whether agreed criteria for identifying substances with endocrine-disrupting properties are available or not. The on-going discussions on such criteria in the sectors of biocides and plant protection products, therefore, can in no way justify the Commission’s decision to postpone the review of the Cosmetics Regulation.

BEUC further considers that the failure to review the Cosmetics Regulation with regard to substances with endocrine-disrupting properties may create unnecessary risks for consumers. The Commission’s decision to postpone the EDC review directly conflicts with the high level of protection sought by the legislator. Political concerns rather than legitimate scientific or technical reasons would thus appear to dictate the delay in completing the EDC review.

**What, in your view, should the institution or body do to put things right?**

The European Commission must complete the review foreseen in Article 15(4) of the Cosmetics Regulation without further delay, and independent of the on-going discussions on EDC criteria in the sectors of biocides and plant protection products. Based on the review, the Commission should, where appropriate, propose amendments to the Cosmetics Regulation to ensure a high level of consumer protection against substances with endocrine-disrupting properties.

**Have you already contacted the EU institution or body concerned in order to obtain redress?**

On 2 February 2016, BEUC wrote to Commissioner Vytenis Andriukaitis to emphasise, among others, the Commission’s failure to perform the EDC review despite the legal obligation to do so no later than 11 January 2015. Commissioner Andriukaitis’ written response dated 13 February 2016 did not address the delayed EDC review.

BEUC again raised the EDC review with the responsible Commission services at a meeting on 3 March 2017. At our request, the delayed EDC review was likewise included on the agenda for the 3 July 2017 meeting of the Working Group on Cosmetic Products.

At the July meeting, the Commission explained that the situation with regard to the EDC review was similar to the situation presented at the March 2017 meeting. The Commission reiterated that the adoption of the draft EDC review report by the College had been postponed in light of the on-going discussions on the EDC criteria in the biocides and plant protection products sectors. The Commission could not provide further information about when the EDC review would be finalised.

**If the complaint concerns work relationships with the EU institutions and bodies: have you used all the possibilities for internal administrative requests and complaints provided for in the Staff Regulations? If so, have the time limits for replies by the institutions already expired?**

Not applicable

**Has the object of your complaint already been settled by a court or is it pending before a court?**

No
Do you agree that your complaint may be passed on to another institution or body (European or national), if the European Ombudsman decides that he is not entitled to deal with it?

Yes

ENDS
Dear Maria,

Thanks for your swift reply. I’m happy to hear that the case is progressing and look forward to the Ombudsman’s opinion!

In the meantime, should new questions arise please do not hesitate to contact us in case you feel we could be of assistance.

All best,

From: DEPASQUALE Maria

Sent: Tuesday, October 2, 2018 10:39 AM

To: (BEUC)

Subject: RE: BEUC complaint re. delayed EDC review of the Cosmetics Regulation

Dear [Name],

Thank you very much for your e-mail.

As Koen rightly mentioned to you, your case is being discussed internally and we hope to finalise it shortly.

Thank you for your offer to help clarify any issues and provide further information. That would not appear to be necessary but it's most kind of you to have offered to do so.

Best wishes,

Maria

European Ombudsman

Maria Depasquale
Principal legal officer

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1 avenue du Président Robert Schuman
CS 30403
F - 67001 Strasbourg Cedex

T. + 33 (0)3 88 17 23 13
F. + 33 (0)3 88 17 90 62
www.ombudsman.europa.eu
Dear Ms Depasquale,

I write in follow-up to a recent exchange with your colleague, Koen Roovers. I had the pleasure to meet Koen a few weeks back, and mentioned in this context BEUC’s complaint to the Ombudsman regarding the delayed review of the Cosmetics Regulation with regard to endocrine disruptors (Complaint 2111/2017/MDC).

We understand that the review is still blocked within the Commission, although it could be published before the end of the year. For your information, I attach the overview of the Commission's plans and timeline I previously sent to Koen. I hope you will find it useful.

I understand by Koen’s reply (attached) that certain aspects related to our complaint is still under consideration. I therefore wanted to see if we in any can help clarify these issues and/or provide you with additional information?

I look forward to your reply.

Best wishes,

Rue d’Arlon 80
B-1040 Brussels
Tel. +32(0)2
Mob. +32(0)
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Consult our entry in the EC register for interest representatives
Think before you print
Dear Koen,

Thanks again for interesting talk just now – it was a pleasure meeting you and Fergal! Please also convey my warmest greetings to Rosita!

I am especially happy to have met you since I meant to follow up with your colleague, Ms Maria Depasquale regarding BEUC’s complaint over the Commission’s delay in finalizing the review of the Cosmetics Regulation with regard to endocrine disruptors (Complaint 2111/2017/MDC).

As mentioned just now, and also explain in our complaint (attached), we understand that the Commission has already finalized the review, but delays the adoption and publication of its conclusions. The latest intelligence we have from sources within the Commission is that the review report was in inter-service consultation before the summer break (in July), but that the finalization was again delayed, possibly by the College itself, as a result of disagreements among the Commission services over the Commission Communication ‘towards a more comprehensive EU framework on endocrine disruptors’. Should this be the case it again seems to confirm the concern expressed in our complaint that political and not technical/scientific considerations as claimed by the Commission explains the delayed review.

My understanding is the Communication is meant to form the ‘chapeau’ for a package on endocrine disruptors, which will also include the delayed Cosmetics review. At this stage, we have no information on the Communication’s timeline for the Communication or the review, although the Communication was initially foreseen during Q3 2018 – as you may also have seen the Communication was confirmed in the letter of intent send by President Juncker to President Tajani and Chancellor Kurz earlier this week. We hope to learn more about the timeline when we meet the Commission services responsible for coordinating the Communication next week – and will of course keep you in the loop.

In the meantime, I sincerely hope it will be possible for the EU Ombudsman to finalize her investigation before the Commission communicates the results of the EDC review (understanding of course the number of ongoing cases).

I am of course happy to answer any questions you or your colleagues might have!

Have a lovely weekend!

Best wishes,

Rue d'Arlon 80
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Consult our entry in the EC register for interest representatives
Think before you print
Dear Maria,

Sorry to come back to you only now.

The timeline for the adoption of the review of Regulation (EC) No 1223/2009 with regard to endocrine disruptors is still under discussion. Indeed, the Commission launched an inter-service consultation in summer 2018 and the result is being assessed. Following such ongoing internal discussions, a decision may be expected soon.

Best regards,

Many thanks!

Kind regards,

Maria

I’ll check.

Dear [name],
I hope this e-mail finds you well.

I have a question regarding case 2111/2017/MDC please.

In the Commission’s comments of 27 March 2018 (to the Ombudsman), the Commission stated that it intended to present the review of Regulation (EC) No 1223/2009 (the Cosmetics Regulation) shortly. The complainant’s representative in that case has informed us that he has heard that the review report was in inter-service consultation before the summer break (in July). Could you please confirm whether any progress has been made and whether the review report is expected to be published very soon?

Many thanks in advance.

Kind regards,

Maria

European Ombudsman
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F - 67001 Strasbourg Cedex
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F. + 33 (0)3 88 17 90 62
www.ombudsman.europa.eu
Dear Maria,

Sorry to spam you: the Commission did in fact publish the EDC review yesterday, although this was not communicated as part of the Communication on endocrine disruptors (no mention or link with the press material). The report is available here: http://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-739-F1-EN-MAIN-PART-1.PDF

Results and conclusions as expected. As previously stated, the Commission again maintains that the EDC criteria developed in the context of EU pesticides and biocides legislation should be taken into account for the purposes of the review - although curiously the report neglects to explain how this has been done in practice.

All best,

From: DEPASQUALE Maria
Sent: 07 November 2018 20:31
To: (BEUC)
Subject: Re: BEUC complaint re. delayed EDC review of the Cosmetics Regulation

Dear Maria,

As you may have seen, the Commission today published its strategy on endocrine disruptors: http://europa.eu/rapid/press-release_IP-18-6287_en.htm

Surprisingly, the strategy does not mention the review of the Cosmetics Regulation. Instead, the Commission announces a Fitness Check of relevant EU legislation on endocrine disruptors, including cosmetics. At this stage, the Commission has unfortunately released no further details on the Fitness Check.

All best,

From: (BEUC)
Sent: 02 October 2018 11:18
To: DEPASQUALE Maria
Subject: RE: BEUC complaint re. delayed EDC review of the Cosmetics Regulation

Dear [name],

You're most welcome.
Thank you once again for your kind offer.
Best wishes,
From: [REDACTED] (BEUC)  
Sent: 02 October 2018 11:16  
To: DEPASQUALE Maria  
Subject: RE: BEUC complaint re. delayed EDC review of the Cosmetics Regulation  

Dear Maria,

Thanks for your swift reply. I’m happy to hear that the case is progressing and look forward to the Ombudsman’s opinion!

In the meantime, should new questions arise please do not hesitate to contact us in case you feel we could be of assistance.

All best,

From: DEPASQUALE Maria  
Sent: Tuesday, October 2, 2018 10:39 AM  
To: [REDACTED] (BEUC)  
Subject: RE: BEUC complaint re. delayed EDC review of the Cosmetics Regulation  

Dear [REDACTED],

Thank you very much for your e-mail.

As Koen rightly mentioned to you, your case is being discussed internally and we hope to finalise it shortly.

Thank you for your offer to help clarify any issues and provide further information. That would not appear to be necessary but it's most kind of you to have offered to do so.

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Maria

European Ombudsman

Maria Depasquale  
Principal legal officer  
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F. +33 (0)3 88 17 90 62  
www.ombudsman.europa.eu

From: [REDACTED] (BEUC)  
Sent: 02 October 2018 10:23  
To: DEPASQUALE Maria  
Cc: BEUC - Safety <Safety@beuc.eu>  
Subject: BEUC complaint re. delayed EDC review of the Cosmetics Regulation  

Dear Ms Depasquale,

I write in follow-up to a recent exchange with your colleague, Koen Roovers. I had the pleasure to meet Koen a few weeks back, and mentioned in this context BEUC’s complaint to the Ombudsman regarding the delayed review of the Cosmetics Regulation with regard to endocrine disruptors (Complaint 2111/2017/MDC).

We understand that the review is still blocked within the Commission, although it could be published before the end of the year. For your information, I attach the overview of the Commission’s plans and timeline I previously sent to Koen. I hope you will find it useful.
I understand by Koen’s reply (attached) that certain aspects related to our complaint is still under consideration. I therefore wanted to see if we in any can help clarify these issues and/or provide you with additional information?
I look forward to your reply.

Best wishes,

---

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Consult our entry in the EC register for interest representatives
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From: [REDACTED] (BEUC) [REDACTED]
Sent: 14 September 2018 16:42
To: ROOVERS Koen [REDACTED]
Cc: BEUC - Safety <Safety@beuc.eu>
Subject: BEUC complaint re. delayed EDC review of the Cosmetics Regulation

Dear Koen,

Thanks again for interesting talk just now – it was a pleasure meeting you and Fergal!! Please also convey my warmest greetings to Rosita!

I am especially happy to have met you since I meant to follow up with your colleague, Ms Maria Depasquale regarding BEUC’s complaint over the Commission’s delay in finalizing the review of the Cosmetics Regulation with regard to endocrine disruptors (Complaint 2111/2017/MDC)

As mentioned just now, and also explain in our complaint (attached), we understand that the Commission has already finalized the review, but delays the adoption and publication of its conclusions. The latest intelligence we have from sources within the Commission is that the review report was in inter-service consultation before the summer break (in July), but that the finalization was again delayed, possibly by the College itself, as a result of disagreements among the Commission services over the Commission Communication ‘towards a more comprehensive EU framework on endocrine disruptors’. Should this be the case it again seems to confirm the concern expressed in our complaint that political and not technical/scientific considerations as claimed by the Commission explains the delayed review.

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the Communication or the review, although the Communication was initially foreseen during Q3 2018 – as you may also have seen the Communication was confirmed in the letter of intent send by President Juncker to President Tajani and Chancellor Kurz earlier this week. We hope to learn more about the timeline when we meet the Commission services responsible for coordinating the Communication next week – and will of course keep you in the loop.

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I am of course happy to answer any questions you or your colleagues might have!

Have a lovely weekend!

Best wishes,

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Consult our entry in the EC register for interest representatives
Think before you print
COMPLAINT: 2111/2017/MDC

Confidentiality requested by the complainant (Article 2.2 of the Implementing Provision)? If yes, explain here for what information/documents

No

Confidentiality necessary for the protection of the legitimate interests of the complainant or of a third party (Article 9.7 of the Implementing Provisions)? If yes, explain here for what information/documents

No

Resource indicator (the expected total time that the case is likely to demand)

Standard

Surname(s)

First name(s)

Legal person name

BEUC - The European Consumer Organisation

'Represented by' (if applicable)

Institution, body, office, or agency complained against

("Top ten" list for the last two years.)

European Commission
SUMMARY

Title
The European Commission’s failure to carry out a review, in 2015, of the Cosmetics Regulation with regard to substances with endocrine-disrupting properties

Key issues, facts and background

Key issue
The key issue is the Commission’s failure to complete the review of the Cosmetics Regulation with regard to substances with endocrine-disrupting properties, despite its obligation, laid down in Article 15(4) of the Cosmetics Regulation, to review the Regulation “at the latest on 11 January 2015”.

Facts and background
Article 15(4) of Cosmetics Regulation (EC No 1223/2009) requires the European Commission to review ("the Commission shall review") the Cosmetics Regulation with regard to substances with endocrine-disrupting properties (i.e. chemicals which may alter individuals’ hormone systems), “when Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015” (emphasis added). According to the complainant (an association of consumer organisations which is a member of a Commission Expert Group - the ‘Working Group on Cosmetic Products’), despite this unambiguous deadline, the Commission has failed to complete the review of the Regulation with regard to substances with endocrine-disrupting properties (hereinafter the ‘EDC review’). The complainant states that the failure to complete the review may endanger the health of millions of consumers across the EU.

In a June 2016 Communication (to the Parliament and Council) on endocrine disruptors, the Commission declared that the EDC “review is overdue. A screening exercise of certain

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2 The complainant argues that, since January 2015, it has repeatedly expressed its concern about the delayed EDC review, which may create unnecessary health risks for consumers. According to the complainant, sufficient evidence links endocrine-disrupting chemicals (EDCs) to a range of severe diseases and disorders, including infertility and cancer. Cosmetics ingredients with endocrine-disrupting properties represent a significant, potential source of cumulative consumer exposure to EDCs – a fact compellingly demonstrated by EU consumer organisations. Consumers are in frequent, intimate and often prolonged contact with cosmetic and personal care products: a survey of more than 2,300 people found that the average adult uses nine personal care products each day. This aggregate figure however hides significant variations. One in four women for example use at least 15 products daily, according to the same survey. The complainant states that cosmetic and personal care products are thus major direct sources of consumer exposure to potential EDCs, including for vulnerable groups, such as pregnant and breast-feeding women, children and persons with compromised immune responses.
3 Communication from the Commission to the European Parliament and the Council on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products, COM/2016/0350 final, available
cosmetic ingredients that has been contracted by the Commission is close to completion. The
Commission will present the review by the end of the year” (emphasis added). Moreover, on 8
July 2016, in reply to a Parliamentary question, the Commission stated that “before end-2016,
the Commission will complete the review and communicate the results.”

However, the complainant reports that this has not happened. Instead, at the meeting of the
Working Group on Cosmetic Products held on 14 March 2017, the Commission informed the
members of the Working Group that “[…] a draft report on the evaluation of the Cosmetics
Regulation as regards endocrine disruptors ... was prepared in view of its adoption by the
College by the end of 2016. However, [the Commission] is still examining the draft report and
its adoption was postponed in light of the on-going discussions on the scientific criteria for
the definition of [endocrine disruptors] in the sectors of biocides and plant protection
products” 4 (emphasis added).

The complainant considers that the on-going discussions on the Commission’s proposed
scientific criteria to determine endocrine-disrupting properties in the sectors of biocides and
plant protection products (hereinafter the ‘EDC criteria’) do not justify the Commission’s
decision to postpone the EDC review.

In the Biocidal Product Regulation (Regulation (EU) No 528/2012) 5 and the Plant Protection
Products Regulation (Regulation (EC) No 1107/2009) 6, the European Parliament and Council
set December 2013 as the deadline for the Commission to adopt EDC criteria. In accordance
with the Biocidal Products Regulation in particular, the Commission was to adopt delegated
acts setting out EDC criteria by 13 December 2013 at the latest. The Commission’s failure to
adopt such criteria under the Biocidal Products Regulation was declared unlawful by the
General Court of the European Union in December 2015 7.

According to the complainant, that fact does not exonerate the Commission from the
obligation to carry out the EDC review. On the contrary, the specific formulation of Article
15(4) of the Cosmetics Regulation, as well as the absence of a legal reference to either the
Plant Protection Products Regulation or the Biocidal Products Regulation demonstrate that
the EDC review obligation exists in its own right and independently of the Commission’s
obligation to develop EDC criteria in other sectors 8. The complainant goes on to state that

at: http://eur-lex.europa.eu/legal-
content/EN/TXT/PDF/?uri=CELEX:52016DC0350&gid=1512988202902&from=EN

4 Extract from the minutes of the Meeting of the Working Group (WG) on Cosmetic Products, 14 March
2017, available at:
http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=34018&no=2


concerning the placing of plant protection products on the market and repealing Council Directives

7 See the judgment of the General Court of 16 December 2015 in Case T-521/14, Sweden v European
Commission, ECLI:EU:T:2015:976. Sweden was supported by the Parliament, the Council and a number
of Member States.

8 The complainant also contends that the EDC criteria proposed by the Commission are developed
exclusively based on a sectorial view (biocides/pesticides). It is therefore unclear if the proposed criteria

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this conclusion is further corroborated by the travaux préparatoires for the Cosmetics Regulation. These state, according to the complainant, the legislator’s intention that the Commission must complete the EDC review no later than 5 years after the date of entry into force of the Regulation.

In other words, the legislature set an unequivocal deadline for the Commission to review the Cosmetics Regulation – regardless of whether agreed criteria for identifying substances with endocrine-disrupting properties are available. The ongoing discussions on such criteria in the sectors of biocides and plant protection products, therefore, cannot justify the Commission’s decision to postpone the review of the Cosmetics Regulation.

According to the complainant, the Commission’s decision to postpone the EDC review directly conflicts with the high level of protection sought by the legislature. Political concerns rather than legitimate scientific or technical reasons would thus appear to dictate the delay in completing the EDC review.

It should be noted that the complainant wrote to the Commissioner for Health and Food Safety on 2 February 2016. The subject matter of that letter was not, strictly speaking, the revision of the Cosmetics Regulation. In its letter, the complainant urged the Commissioner “to take immediate action to ensure better protection of consumers against hormone-disrupting chemicals.” The complainant informed the Commissioner that under EU biocides, pesticides and cosmetics laws, the Commission is obliged to adopt scientific criteria identifying hormone-disrupting chemicals. It stated that all legal deadlines have passed without the Commission having taken action. It added that this failure to act is of major concern as it is impossible to restrict or ban the most harmful of these chemicals without such legal criteria. The complainant referred to the General Court’s ruling (T-521/14, Sweden v Commission referred to above) laying down that (i) the failure to adopt scientific criteria is unlawful, (ii) an impact assessment is not required as a precondition for setting criteria, and (iii) the Commission is obliged to abide by the deadlines unambiguously set in legislation. The

can be applied to other sectors or product groups, such as cosmetics. By way of example, the complainant cites a report of the Dutch National Institute for Public Health and the Environment (RIVM) (available at: http://www.rivm.nl/dsresource?objectid=ef84741f-cda2-4791-9995-4efeb7a8fc90&type=pdf&disposition=inline ) which concludes that “due to the ban on animal testing for cosmetic ingredients effective since 2013, it is not possible to identify a chemical as an EDC based on the draft EU criteria. If a chemical is only used in cosmetic products, it will be extremely difficult to differentiate between a potential EDC and EDC.”

The complainant states that cosmetic products are a significant, direct sources of consumer exposure to potential EDCs, including for vulnerable groups, such as pregnant and breast-feeding women, children and persons with compromised immune responses. Cosmetics ingredients with endocrine-disrupting properties should therefore be regulated consistent with substances of equivalent concern, such as those that cause cancer, change DNA or are toxic to reproduction (CMRs). The Cosmetics Regulation prohibits use of known, presumed and suspected CMR substances, and a parallel approach is needed for substances with endocrine-disrupting properties to achieve a high level of consumer protection. The proposed EDC criteria however only allow for the identification of known and presumed EDCs, but exclude suspected (potential) EDCs. This suggests that to achieve the objectives of the Cosmetics Regulation, specifically a high level of protection, the proposed EDC criteria will most certainly need to be modified and further developed. According to the complainant, since the Commission has set aside the commitment under the 7th Environmental Action Programme to develop ‘horizontal’ EDC criteria, the delay with respect to adopting the EDC criteria developed for the biocides and pesticides sectors cannot justify the failure to complete the EDC review for cosmetic products.
complainant expressed its surprise at the Commission’s decision to disregard the Court’s ruling and proceed with the impact assessment, rather than swiftly adopt legal criteria.

The complainant did not annex a copy of the Commissioner’s reply to this letter but states that the Commission’s reply of 13 February 2016 did not address the delayed EDC review.

The complainant says that it raised the issue of the EDC review with the responsible Commission services at a meeting on 3 March 2017 and that at its request, this issue was included in the agenda for the meeting of the Working Group on Cosmetic Products of 3 July 2017. In fact the complainant annexed a copy of an e-mail dated 6 June 2017, sent by its representative to a legal officer of the Commission, in which the complainant’s representative states as follows: “in light of the ongoing delay in adopting criteria to identify endocrine-disrupting properties under the Biocidal Products Regulation, we would appreciate if the Commission could clarify the timeline for concluding the review of the Cosmetics Regulation with regard to Endocrine Disruptors foreseen in article 15(4), including what concrete steps the Commission intends to undertake before concluding the review. Does the Commission for example intend to create an opportunity for stakeholders to give input to the review in line with the commitments set out in the Commission’s Better Regulation agenda? We would also appreciate if the Commission would share its assessment of whether the EDC criteria as currently proposed under the Biocidal Product Regulation could be applied to cosmetics products or if special allowance would be required to achieve the level of consumer protection desired by the Legislator?”

The Commission’s reply (of 23 June 2017) was that the complainant’s suggestion would be included in the agenda of the Working Group on Cosmetics Products of 3 July 2017.

Object of the complaint

The complaint is that the Commission has failed to complete the review of Regulation (EC) No 1223/2009 (the Cosmetics Regulation) with regard to substances with endocrine-disrupting properties, despite its obligation, laid down in Article 15(4) of the Cosmetics Regulation, to review the Regulation with regard to those substances “at the latest on 11 January 2015”.

Supporting arguments by the complainant

1. The legislature set an unequivocal deadline for the Commission to review the Cosmetics Regulation, regardless of whether agreed criteria for identifying substances with endocrine-disrupting properties are available. It seems that the ongoing discussions on the scientific criteria for the definition of endocrine disruptors in the sectors of biocides and plant protection products (the ‘EDC criteria’)

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postpone the review of the Cosmetics Regulation. In any event, it is unclear whether the EDC criteria can be applied to other sectors or product groups (besides biocides and plant protection products), such as cosmetics.

2. The Commission’s decision to postpone the review may create unnecessary risks for consumers and conflicts with the Cosmetics Regulation’s objective of ensuring a high level of protection of human health.

**Claim(s)**

The complainant’s desired outcome is the completion of the review envisaged by Article 15(4) of the Cosmetics Regulation without further delay.

**Internal analysis and proposal**

**Admissibility**

The complainant is based in Belgium, its complaint is against the European Commission, and it has not brought proceedings in court about the matter complained about. The complainant may also be considered to have undertaken prior administrative approaches, since it has contacted the Commission asking it to clarify the timeline for concluding the review of the Cosmetics Regulation. Although the Commission should have reviewed the Cosmetics Regulation by 11 January 2015, that is, more than two years ago, and the complainant may be presumed to have been well aware of that deadline, it should be noted that the Commission had initially declared that the review was “long overdue” and that it was to be completed by the end of 2016. Thus, the complainant may not have felt the need to bring a complaint to the Ombudsman at the time, in view of the Commission’s commitment. It was not until 14 March 2017 that the Commission stated that it had decided to postpone the review. Thus, it may be considered that the complaint was brought within two years of the date on which the facts on which it is based came to the complainant’s attention. The complaint is thus admissible.

**Substantive assessment**

As stated in the preceding paragraph, the Commission itself has admitted that the review of the Cosmetics Regulation is “long overdue”. Although there may be value in the Commission’s approach to await the outcome of the discussions on the scientific criteria for the definition of endocrine-disruptors in the sectors of biocides and plant protection products before completing the review of the Cosmetics Regulation, the complainant rightly...

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In point 3.1.1. of the minutes, it is stated that “[...] a draft report on the evaluation of the Cosmetics Regulation as regards endocrine disruptors ... was prepared in view of its adoption by the College by the end of 2016. However, [the Commission] is still examining the draft report and its adoption was postponed in light of the on-going discussions on the scientific criteria for the definition of [endocrine disruptors] in the sectors of biocides and plant protection products”.
points out that the deadline for carrying out the review, set out in Article 15(4) of the Cosmetics Regulation is unequivocal. It therefore appears that no matter how cogent the arguments in favour of postponing the review may be, any postponement of the review is illegal. It is therefore proposed to open an inquiry into this complaint and to ask the Commission to reply to the complainant’s allegation (and supporting arguments).

The following paragraph could also be inserted in the opening letter: “The Commission’s reply should deal, in particular, with the question of whether the Commission’s obligation to review the Regulation by 11 January 2015 is an unequivocal obligation. If the Commission believes that it had the discretion not to complete its review by 11 January 2015, please explain in detail why the Commission takes this view. Given that three years have now elapsed since the review was required to be completed, it would be helpful to know what the Commission now proposes to do in order to ensure that the review is completed with the minimum of further delay.”

Remember to check the EO’s publication policy and to give the necessary instructions to your Unit Assistant about publication of the relevant documents if needed!
### DETAILED DATA RELATED TO COMPLAINANT

#### Language of complaint

EN

#### Country of address

Belgium

#### Nationality


#### 'Kind' of complainant (exhaustive lists)

<table>
<thead>
<tr>
<th>If natural person:</th>
<th>Kind specific:</th>
</tr>
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<tbody>
<tr>
<td>- CHOOSE ITEM -</td>
<td>- CHOOSE ITEM -</td>
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<table>
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<tr>
<th>If legal person:</th>
<th>Kind specific:</th>
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<tbody>
<tr>
<td>Association, organisation, NGO</td>
<td>-</td>
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</tbody>
</table>
PERSONAL DATA OF THIRD PARTIES

Article 12(1) of Regulation 45/2001 provides for a duty to inform third parties individually about the processing of their personal data. Please carefully check the points below and consult the guidelines for CHs.

Are there any personal data of third parties in the complaint?  yes ☒ no ☐

If the answer is no: there is no need to assess any further.

If the answer is yes: is the data relevant for the inquiry?  yes ☐ no ☒

Please explain which categories of third-party personal data are deemed relevant or irrelevant for the inquiry:

The third-party data is irrelevant because it concerns names and contact details of the officials of the institution and the complaint is against the institution and not against the officials. ☒

If other, please explain:

If only irrelevant data are present, there is no need to assess any further.

If relevant data are present, do you have evidence that the third party has full knowledge about the complaint to the Ombudsman, including his or her personal data, and which institution is complained about (Article 12(1) of Regulation 45/2001)?  yes ☐ no ☒

Please explain:

If the answer is yes: there is no need to assess any further.

If the answer is no, would it be either impossible or disproportionate to inform the third party individually about the processing of his/her personal data (Article 12(2) of Regulation 45/2001) by the Ombudsman?  yes ☒ no ☐

Please explain:

If the answer is yes: there is no need to assess any further.

If the answer is no, does an exemption of Article 20(1) of Regulation 45/2001 apply (for example, the protection of rights and freedoms of the individuals providing third party data) that would require deferring the fulfilment of the duty to inform the third party at least until the end of the inquiry?  yes ☐ no ☒

Please explain:
If the answer is no: provide the third-party data subject with the information of Article 12(1) of Regulation 45/2001.

If the answer is yes: defer the duty to inform the third party until the end of the inquiry.

NB: At the end of the inquiry, you will have to revisit this data protection issue by filling in the form of which you see a copy here below. The form is contained in the decision template itself.
DATA PROTECTION

If there was a deferral of the duty to inform, under Article 20(1) of Regulation 45/2001, is there still a reason to apply the above exemption after the inquiry is closed?

- yes ☐
- no ☐

Please explain:

If the answer is no: please provide the third-party data subject with the information of Article 12(1) of Regulation 45/2001 and an explanation pursuant to Article 20(3) of that Regulation.

If the answer is yes, decide on continuation of the application of the exemption.
KEYWORDS

All keyword groups 1-3 must be used. For each keyword group, you yourself determine how many keywords should be recorded.

KEYWORD 1 - EU competence area

1. Health and food safety
2. - CHOOSE ITEM -
3. - CHOOSE ITEM -
4. - CHOOSE ITEM -
5. - CHOOSE ITEM -
6. - CHOOSE ITEM -

KEYWORD 2 - Issue

1. Other
2. - CHOOSE ITEM -
3. - CHOOSE ITEM -
4. - CHOOSE ITEM -
5. - CHOOSE ITEM -
6. - CHOOSE ITEM -

KEYWORD 3 - Possible maladministration

1. Failure to follow the law [Article 4 ECGAB]
2. - CHOOSE ITEM -
3. - CHOOSE ITEM -
4. - CHOOSE ITEM -
5. - CHOOSE ITEM -
6. - CHOOSE ITEM -
Dear Ms O'Reilly,

Subject: Complaint by [REDACTED] on behalf of BEUC – the European Consumer Organisation, ref. 2111/2017/MDC

Thank you for the letter of 15 January 2018 addressed to President JUNCKER about the above-mentioned case.

I am pleased to enclose the comments of the Commission regarding this complaint.

Naturally, the Commission remains at your disposal for any further information you may require.

Yours sincerely,

[REDACTED]

Elżbieta Bieńkowska

Enclosure

Ms Emily O'REILLY
European Ombudsman
1, avenue du Président Robert Schuman
B.P. 403
F-67001 STRASBOURG Cedex
Comments of the Commission on a request for information from the European Ombudsman
- Complaint by [REDACTED] on behalf of BEUC – the European Consumer Organisation, ref. 2111/2017/MDC

I. BACKGROUND

The European Ombudsman ('the Ombudsman') has received a complaint against the European Commission from [REDACTED] on behalf of BEUC – the European Consumer Organisation. The complaint concerns the Commission's alleged failure to carry out a review of Regulation (EC) No 1223/20091 ('the Cosmetics Regulation') with regard to substances with endocrine-disrupting properties by 11 January 2015. Subsequently, the Ombudsman sent the complaint to the Commission for comments.

II. THE COMPLAINT

The complainant alleges that the Commission has failed to complete the review of the Cosmetics Regulation with regard to substances with endocrine-disrupting properties 'at the latest on 11 January 2015', despite its legal obligation, laid down in Article 15(4) of the Cosmetics Regulation.

The complainant argues that the deadline set by the legislator for the review is unequivocal and that the ongoing discussions on the criteria for identifying endocrine disruptors in the sectors of biocides and plant protection products cannot justify the Commission's decision to postpone the review. The complainant adds that the failure to complete the review may create unnecessary risks for consumers.

III. THE COMMISSION'S COMMENTS TO THE COMPLAINANT'S ARGUMENTS

Article 15(4) of the Cosmetics Regulation provides that: When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties.

It should be noted that – unlike for example Article 5(3) of Regulation (EU) No 528/2012 on biocide products – Article 15(4) of the Cosmetics Regulation does not require the Commission to adopt a legal act (such as a Regulation or a legislative proposal) with a defined content. Under Article 15(4) the Commission is expected to review the basic Regulation with regard to certain substances, in other words to examine the question of the use in cosmetic products of certain substances which are not subject to specific rules in that Regulation.

At the date of 11 January 2015 laid down in the provision, the 'Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties' were not yet

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available. Indeed, the Commission had been working on the determination of criteria to identify endocrine disruptors (ED), with a focus on biocides and plant protection products, for some years. The Commission carried out a comprehensive impact assessment to analyse different options for defining the criteria for the identification of endocrine disruptors. The roadmap for the impact assessment was published in June 2014. A public consultation took place between September 2014 and January 2015. A screening study analysing which chemicals would be identified as endocrine disruptors under the different options for the criteria was conducted to provide input for the impact assessment. The Commission's Joint Research Centre (JRC) developed a screening methodology, which was then applied by an external independent contractor to screen the available evidence for approximately 600 chemicals. The screening started in May 2015 and sequentially covered active substances used in plant protection and biocidal products, as well as a selection of substances falling under the REACH Regulation, the Cosmetics Regulation and the Water Framework Directive. Therefore cosmetics were considered in the broader context of this work and due to the ongoing impact assessment, it was decided that ensuring coherence throughout the sectors was important, without creating unnecessary risk for consumers and without lowering the level of protection of human health.

In a Communication of 15 June 2016, which accompanied the publication of the Commission draft Regulations for scientific criteria for the determination of endocrine disruptors in the areas of biocides and plant protection products, the Commission set out the science-based decisions underlying the two draft measures. The Communication was accompanied by the finalised impact assessment which presented the state of the science regarding different criteria to identify endocrine disruptors. As stressed by the Commission in that Communication, the topic of endocrine disruptors is complex and no other country had thus far adopted legally-binding scientific criteria to determine what an endocrine disruptor is. In the above-mentioned Communication, the Commission therefore also acknowledged that the review under Article 15(4) of the Cosmetics Regulation was already overdue.

As regards the Commission draft Regulations on endocrine disruptors in the areas of biocides and plant protection products, despite the solid preparatory work underlying these texts, lengthy discussions with Member States ensued in the relevant committees, and substantially delayed their adoption. Between June 2016 and December 2017, representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products discussed the draft criteria at seven occasions and representatives of Member States in the Standing Committee on Plants, Animals, Food and Feed (Section Phytopharmaceuticals - Plant Protection Products – Legislation) discussed the draft criteria at nine occasions. The minutes of all these meetings and the different versions of the draft criteria were published on a dedicated webpage, to ensure maximum transparency. The Delegated Regulation in the area of biocides was thus eventually adopted and subsequently published in November 2017, while the Regulation in the field of plant protection products has not yet been adopted.

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4 https://ec.europa.eu/health/endocrine_disruptors/next_steps

Indeed, by acting under the Regulatory Procedure with Scrutiny\textsuperscript{6}, the first version was rejected by the European Parliament on 4 October 2017 and a new revised version obtained a qualified majority in the Standing Committee in December 2017 and is currently under scrutiny of the European Parliament and of the Council.

As noted by the complainant, the June 2016 Communication also announced that the Commission would present the review of the Cosmetics Regulation with regard to substances with endocrine-disrupting properties by the end of the year 2016. Although the preparation of the document was well advanced, further discussions with Member States were necessary in light of the on-going discussions on the scientific criteria for the definition of endocrine disruptors in the sectors of biocides and plant protection products. Its adoption was therefore postponed.

However, in view of the objective of the Cosmetics Regulation to ensure a high level of protection of human health and given the recent adoption of the criteria for endocrine disruptors in the area of biocides as well as the possible adoption in due course of the criteria in the field of plant protection products, the Commission intends to present the review shortly.

IV. CONCLUSIONS

The Commission is doing its utmost to complete its work in order to present the review of the Cosmetics Regulation shortly. As announced last summer, the Commission is also working on a broader Strategy on endocrine disruptors.

\textsuperscript{6} Article 5\textsuperscript{a} of Decision 1999/468/EC.
Strasbourg, 15/01/2018
Complaint 2111/2017/MDC

Subject: The European Commission’s failure to carry out a review, in 2015, of the Cosmetics Regulation with regard to substances with endocrine-disrupting properties

Dear Mr President,

I have received a complaint from BEUC - The European Consumer Organisation, represented by [name redacted], against the European Commission.

The complaint is that the Commission has failed to complete the review of Regulation (EC) No 1223/2009¹ (the Cosmetics Regulation) with regard to substances with endocrine-disrupting properties, despite its obligation, laid down in Article 15(4) of the Cosmetics Regulation, to review the Regulation with regard to those substances “at the latest on 11 January 2015”.

In support of the complaint, the complainant argues that:

1. The legislature set an unequivocal deadline for the Commission to review the Cosmetics Regulation, regardless of whether agreed criteria for identifying substances with endocrine-disrupting properties are available. The ongoing discussions on the scientific criteria for the definition of endocrine disruptors in the sectors of biocides and plant protection products (the ‘EDC criteria’)², therefore, cannot justify the

Commission’s decision to postpone the review of the Cosmetics Regulation. In any event, it is unclear whether the EDC criteria can be applied to other sectors or product groups (besides biocides and plant protection products), such as cosmetics.

2. The Commission’s decision to postpone the review may create unnecessary risks for consumers and conflicts with the Cosmetics Regulation’s objective of ensuring a high level of protection of human health.

The complainant would like the review envisaged by Article 15(4) of the Cosmetics Regulation to be completed without further delay.

I have decided to open an inquiry into this complaint and I would like to receive a written reply from the Commission to the complaint. The reply should deal, in particular, with the question of whether the Commission’s obligation to review the Regulation by 11 January 2015 is an unequivocal obligation. If the Commission believes that it had the discretion not to complete its review by 11 January 2015, please explain in detail why the Commission takes this view. Given that three years have now elapsed since the review was required to be completed, it would be helpful to know what the Commission now proposes to do in order to ensure that the review is completed with the minimum of further delay.

Please note that I am likely to send your reply and related enclosures to the complainant for comments. If you wish to submit documents or information that you consider to be confidential and which should not be disclosed to the complainant, please include them in a separate annex marked ‘Confidential’. Please feel free to contact our case handler, Ms Maria Depasquale, beforehand (+33 (0)3 88 88 88).

I would be grateful to receive the Commission’s reply within three months of the date of this letter.

Yours sincerely,

Emily O’Reilly
European Ombudsman

Enclosure:
Copy of complaint 2111/2017/MDC

In point 3.1.1. of the minutes, it is stated that “[...] a draft report on the evaluation of the Cosmetics Regulation as regards endocrine disruptors ... was prepared in view of its adoption by the College by the end of 2016. However, [the Commission] is still examining the draft report and its adoption was postponed in light of the ongoing discussions on the scientific criteria for the definition of [endocrine disruptors] in the sectors of biocides and plant protection products”. 2