

EUROPEAN COMMISSION

Health and Food Safety Directorate General

Standing Committee on Biocidal Products

6 October 2022 10:00 – 17:00 Hybrid meeting

CIRCABC Link: <u>https://circabc.europa.eu/ui/group/8b6b0199-c74b-43bd-a9dd-</u> 79bdcae3b825/library/f25acf4d-6726-41e5-acb4-c7721be2d6be?p=1&n=10&sort=name_DESC

MINUTES

Section A <u>Information and/or discussion</u>

A.01 Adoption of the Agenda (*SCBP77-Doc.A.01*)

One item was included in the AOB section, upon request from one Member State, regarding one Union authorisation case discussed at the BPC meeting in June 2022. The agenda was then adopted.

A.02 Adoption of the minutes of the 76th SCBP meeting (*SCBP77-Doc.A.02*)

No Member State had comments on the minutes of the 76th SCBP meeting, which were adopted.

A.03 Exchange of views on the approval of (13Z)-Hexadec-13-en-11-yn-1-yl acetate as an active substance for use in biocidal products of product-type 19 (*SCBP77-Doc.A.03*)

The Commission introduced the background of this item, mentioning the relevant discussion that took place in the last SCBP meeting, where Member States were requested to indicate if they support a more open approval as suggested by the Commission proposal. The Commission clarified its intention not to include the restrictive provision suggested by the BPC Opinion. A recital will be added in the implementing Regulation explaining why the BPC Opinion was not followed on this point (could limit innovation, no justified by certain risks). In the opened newsgroup, three Member States supported the proposal of the Commission for an open approval, while three more supported it with reservations.

During the meeting discussion, three Member States supported the Commission proposal, while another one expressed reservations. One additional Member State declared their support, but they asked to include in the minutes their reservations concerning adaptations of data requirements. The Commission announced its intention to proceed with a draft Implementing

Regulation approving the substance for the associated product-type, and will ask comments on the act by the Member States in the next SCBP meeting.

A.04 Exchange of views on the approval of Alkyl (C12-16) dimethylbenzyl ammonium chloride (C12-16-ADBAC/BKC) as an active substance for use in biocidal products of product-type 2 (*SCBP77-Doc.A.04*)

The Commission introduced the background of this item, highlighting that ECHA organised in August 2022 a dedicated meeting with the evaluating Member State and the three Member States that expressed minority opinions on the BPC Opinion. Despite this meeting, the three Member States retained their reservations on the approval of the substance. The Commission mentioned its intention to proceed with a draft Implementing Regulation approving the substance, based on the BPC Opinion that was supported by majority, despite the three minority opinions.

Two of the Member States that initially expressed minority opinions informed that they would vote against a potential approval. An additional Member State expressed its reservation, mentioning that the BPC Opinion overestimated its arguments on the acceptability of the identified risk on the soil compartment, and it pointed that it would abstain. ECHA clarified that there is no new information provided during the August meeting, and that the risk assessment for the soil compartment has been revised after the environmental working group but only a few days before the adoption of the BPC Opinion.

The Commission concluded that they need to address further the issue with ECHA before proceeding with a decision on PT2. However, they announced their intention to proceed with the approval of the substance for PT1, where the BPC Opinion was adopted by consensus and no minority opinion was expressed.

A.05 Exchange of views on the examination of the renewal of approval of propiconazole for use in biocidal products of product-type 8 (*SCBP77-Doc.A.05*)

The Commission introduced the background of this item and invited the Member States opinions whether they agree with Commission's preliminary conclusions that the derogation to exclusion conditions (a) and (b) of Article 5(2) are not met, but the condition (c) is met, at least for central/northern EU countries.

Two Member States agreed with the Commission's preliminary conclusions. Two additional Member States also agreed with Commission's preliminary conclusions, and pointed that condition (c) is also met for southern EU countries. One of them highlighted that 80% of PT8 biocidal products in their country contain propiconazole. They asked for more time to address whether specific restrictions to the uses of propiconazole are needed. Another Member State mentioned that it needs more time to elaborate if derogation condition (c) is met for all uses, and inquired that IPBC might be considered as an effective alternative for anti-sapstain use. Another Member State agreed with the Commission's preliminary conclusions that pointed that no uses of propiconazole should be restricted. The same country inquired on the possible alternatives of propiconazole in the future. Another Member State concurred with the latest position. Two other Member States mentioned that treated articles of propiconazole are available to the general public and there is a need to harmonize risk mitigation measures. Another Member State underlined that the observed resistance of *aspergillus sp.* to azoles should be taken into consideration and asked from Commission to provide any latest updates.

The Commission clarified that there are no updates on the azoles resistance assessment. It would welcome a parallel analysis on possible substitutes of propiconazole by Member States. Based on the discussion, the Commission concluded that derogation conditions (a) and (b) are not met for propiconazole renewal, but condition (c) might be met and needs further input by the SCBP members to conclude on it. Thus, the Commission announced its intention to open a newsgroup on derogation condition (c), with a deadline set on 31 October 2022. Member States were also invited to consider whether certain uses should be no longer allowed.

A.06 Exchange of views on the examination of the approval reaction products of paraformaldehyde and 2- hydroxypropylamine (ratio 1:1) (originally notified as HPT) for use in biocidal products of product-types 2, 6, 11 and 13, and for Reaction products of paraformaldehyde and 2- hydroxypropylamine (ratio 3:2) (originally notified as MBO) for product-types 2, 6, 11, 12 and 13 (*SCBP77-Doc.A.06*)

The Commission introduced the background of this item, summarising the history of the two active substances, the ECHA public consultation on alternatives based on Article 10(3) of BPR (held at the end of 2016), the public consultation on derogation to exclusion criteria based on Article 5(2) of BPR (held in 2017) and the BPC Opinions of 2022 updating information on ED properties. The Commission presented in the SCBP77-Doc.A.06 document a Table including possible alternatives of the two substances for each PT, but clarified that this analysis should be considered as preliminary. Finally, the Commission asked the feedback by the Member States on a series of questions stated in the SCBP77-Doc.A.06 document (Section 6), including whether Article 5(2) derogation conditions (a, b, c) are met or not.

A Member State mentioned that they asked for information on alternatives from stakeholders but received no input. The same Member State underlined that the derogation conditions (a) and (b) of Article 5(2) are not met for any PTs. On the borderline between the proposed use on PT2 *vs* PT13, they declared support that it falls under PT2. Another Member State pointed that, based on stakeholders input, the use of RP 3:2 is needed for fuel preservation (diesel plague) and for production hygiene in the paint industry (pipe cleaning). They mentioned their intention to provide more information on the matter.

The Commission informed the SCBP members its intention to ask ECHA a specific updated opinion on the availability of alternatives of the two active substances for each of the PTs. It will also open a newsgroup for the Member States to provide feedback on the questions of Section 6 of the SCBP77-Doc.A.06 document, with a deadline set on 31 October 2022.

A.07 Exchange of views on the availability and suitability of alternatives to hexaflumuron (PT18), and discussion on the utility of specific Article 75(1)(g) requests to ECHA (*SCBP77-Doc.A.07*)

The Commission introduced the background of this item, summarizing the conclusions of the BPC Opinion on the availability of alternatives of hexaflumuron, and asked the view of the Member States. The Commission also made an analysis on the utility of a specific ECHA opinion (and Article 75(1)(g) request) on the availability and suitability of alternatives to substances meeting the exclusion criteria at the beginning of the examination of the applications by the evaluating Competent Authorities. The Commission proposed to not regularly submit anymore these kind of Article 75(1)(g) requests to ECHA, as the BPC is already requested to do this work as part of the normal renewal process.

When it comes to the BPC conclusions of hexaflumuron, four Member States agreed with them. One Member State mentioned that hexaflumuron is needed for the control of tropical termite species, but also for termites found in continental Europe, considering the accidental introductions of tropical termites in continental Europe and the possible need to tackle both tropical and continental Europe termites. Another Member State shared the concern on invasive termite introductions into continental Europe, although not having a strong opinion about it. The Commission concluded that the SCBP members endorse the BPC conclusions and advised the evaluating Member State to proceed with its renewal procedure.

When it comes to continuing making Article 75(1)(g) requests to ECHA, a Member State mentioned that this kind of request is needed to ensure high quality output, and asked from Commission and ECHA to establish dedicated groups responsible on handling Article 10(3) alternatives analysis and Article 5(2) derogation conditions consultations. Two Member States declared that they would prefer to retain these kind of Article 75(1)(g) requests. Another Member State pointed that it has no strong view on this. Another Member State proposed to retain these kind of requests until the ECHA guidance on alternatives is fully implemented. A Member State mentioned its intention to provide written comments on the matter.

ECHA mentioned that the guidance on the alternatives will be adopted in November 2022. It highlighted that this kind of mandate should be integrated in the normal work process, and that it should not be considered as a distinct/separated item of the process. On the Article 5(2) derogation conditions, ECHA pointed that this kind of analysis is in the remit of the Commission and SCBP and not of the BPC.

The Commission supported ECHA's position that the analysis of alternatives should be integrated in the normal work process and that high quality should be always expected. Having in mind the imminent adoption of the ECHA guidance on the analysis of alternatives, the Commission concluded that these kind of requests on alternatives should not be retained as a distinct/separated item of the process for substances meeting the exclusion criteria, but should be normally integrated within the examination procedure of the substances.

A.08 Update on the application for approval of ethylene oxide as an active substance for use in biocidal products of product-type 2

The Commission informed on the state of play of this active substance. The Commission's Legal Service clarified that the proposed use by the applicant to apply Ethylene Oxide (EtO) for disinfecting single-use medical devices at the manufacturing site before packaging is covered by the scope of the Regulation on medical devices (MDR), and therefore falls outside the scope of the BPR. Subsequently, the applicant indicated that they would consider investigating the use of EtO for: a) sterilisation of pharmaceutical products; b) sterilisation of packaging - intended for either medical devices or pharmaceuticals, but without the product itself being present during sterilisation; and c) sterilisation of 'combi-products' which contain elements defined in both medical device and medicines regulations. Based on the recent clarification by the Legal Service it is clear that the use (b) for the sterilisation of packaging intended for medical devices is covered by the scope of the MDR. The question remains whether the uses (a) and (b - for sterilisation of packaging intended for pharmaceutical products) fall under the Medicinal Products Regulation (MPR) or the BPR, and also whether the use (c) sterilisation of 'combi-products' falls under the scope of the MDR, MPR or BPR. The Commission informed that it is having internal discussions with Commission colleagues handling the MDR and MPR on the matter, and that the will inform the SCBP members on any updates. One Member State informed that it plans to check the matter with its national authorities.

Section B <u>Draft(s) presented for an opinion</u>

- **B.01** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision not approving 1,2-benzisothiazol-3(2H)-one as an active substance for use in biocidal products of product type 10 (*SCBP77-Doc.B.01*)
- **B.02** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision not approving epsilon-metofluthrin as an active substance for use in biocidal products of product type 19 (*SCBP77-Doc.B.02*)
- **B.03** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision not approving chloramin B as an active substance for use in biocidal products of product types 2, 3, 4, 5 (*SCBP77-Doc.B.03*)
- **B.04** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision not approving silver nitrate as an active substance for use in biocidal products of product type 7 (*SCBP77-Doc.B.04*)

The Commission introduced the background of the items B.01 - B.04 together, since they are similar draft decisions. No comments were received from the SCBP members.

The Commission indicated that the drafts would be submitted to the vote of the Committee by written procedure as early as possible after the meeting.

Outcome of the vote by written procedure that took place between 18 October and 31 October 2022: favourable opinion

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision postponing the expiry date of the approval of propiconazole for use in biocidal products of product-type 8 (*SCBP77-Doc.B.05*)

The Commission introduced the background of this item. One Member State mentioned that it would abstain from voting because the active substance meets the exclusion criteria. One Member State underlined its concerns about the observed resistance of *aspergillus sp.* to azoles and therefore would abstain from voting. Another Member State agreed with the Commission proposal. No other comments were received by the SCBP members.

The Commission indicated that the draft would be submitted to the vote of the Committee by written procedure as early as possible after the meeting.

Outcome of the vote by written procedure that took place between 18 October and 31 October 2022: favourable opinion

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Active chlorine based products BPF - CID LINES NV" (*SCBP77-Doc.B.06*)

The Commission recalled that this application was presented and agreed by the Committee at its June meeting. However, the voting procedure following that meeting did not include this application as one Member (the concerned Member State) expressed concerns about the use of products classified as skin corrosive by pressure spraying, and that this classification requires workers to not be exposed to corrosive substances.

This issue was discussed at the Human Health Working Group and a consensus was reached to request the evaluating competent authority (eCA) to propose personal protective equipment based on a qualitative risk assessment. A discussion took place on the matter at the BPC meeting of 6 October 2021 and a majority of members supported the views of the eCA as regard the type of protective equipment to be used by workers. A minority opinion was filed by the concerned Member State that considered that no protective equipment would enable to reduce the risks to no exposure.

At the BPC-44, an application for Union authorisation containing products with the same active substance and substances of concerns in the similar concentration leading to the same classification as skin corrosive was discussed. The BPC-44 concluded that the use of products classified as skin corrosive should not be recommended for use by pressure spraying. This conclusion is in line with the views of the concerned Member State.

The Commission is concerned that the BPC concluded that these products could be authorised in one case and not in another one. The Commission therefore asked ECHA to identify if relevant use parameters of these products could explain these diverging conclusions.

The Commission also informed that the Directorate General Employment, social affairs and inclusion (DG EMPL) was consulted for its opinion on the matter, as this is related to workers protection issues. DG EMPL was not in a position to express concrete recommendations without information on exposure data, but clarified that at least a FFP3 protection level should be appropriate if harmful substances do not enter the gas phase.

The eCA expressed its strong disappointment on the current discussions as the matter was discussed in details at various working meetings and was closed by the BPC. The eCA also argued that the future of Union authorisations would be at stake if the conclusions endorsed by the BPC in one case are jeopardised by the conclusion of another case.

The Commission recalled its responsibility in authorising biocidal products for the union, and the responsibility of all Member States and ECHA in ensuring consistency in the decision and ensuring safety. In that context, the Commission needs to clarify why the risks are considered acceptable by the BPC in one case and not acceptable in another case although they seem very similar. The Commission concluded that pending future clarifications, the draft authorisation decision will not be subject to vote by the Standing Committee.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product "Arche chlorine" (*SCBP77-Doc.B.07*)

The Commission informed that the application was discussed multiple times in previous meetings. During the last meeting, the Standing Committee supported the preparation of a legal act granting the authorisation. Since then, the Commission has been in contact with the authorities of one Member State to adjust the terms and conditions of the authorisation specifically to its territory following their request under Article 44 (5) of the BPR.

That Member State justified its request on the grounds of public policy and the protection of health and life of humans. The Standing Committee had no comment on the draft proposal. The Commission indicated that the draft would be submitted to the vote of the Committee by written procedure as early as possible after the meeting.

Outcome of the vote by written procedure that took place between 25 October 2022 and 18 November 2022: favourable opinion

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Hypo Chlor product family" (*SCBP77-Doc.B.08*)

The Commission briefly introduced the content of the application and explained that one meta SPC was not recommended for authorisation by the BPC because it was not possible to set a shelf life. The second SPC was split because it contained products with different classifications. A long-term storage stability test for products in meta-SPCs 2A and 2B to confirm the proposed shelf life of 24 months is requested from the applicant.

The Commission added that three Member States filed a minority opinion with regard to the content of chlorates in aged products. At the beginning of the storage stability test, the amount of chlorate was outside the range of the specifications set for sodium hypochlorite although the manufacturer used a reference source to formulate its product.

The BPC followed the assessment of the eCA that demonstrated that the presence of chlorates would not increase the risks for human health or reduce the efficacy of the product at the end of the storage stability test. However, for two concerned Member States, another stability test should have been requested whereas for the third authority, the product should not be authorised. The Commission also recalled that sodium hypochlorite is prone to quick degradation upon exposure to temperature above 20°C and over time.

Two Member States indicated that they would vote against the proposal while a third one informed it would abstain.

Outcome of the vote by written procedure that took place between 25 October 2022 and 18 November 2022: favourable opinion

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision not granting a Union authorisation for the single biocidal product "Insecticide Textile Contact" (*SCBP77-Doc.B.09*)

No draft was presented to the SCBP for this meeting. The Commission informed that the applicant will be informed on the intention of the non-authorisation before the draft will be scheduled for the next SCPB meeting.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation correcting Implementing Regulation (EU) 2021/1044 as regards the period of validity of the Union authorisation for the single biocidal product 'Pesguard® Gel'. (*SCBP77-Doc.B.10*)

The SCBP took note of Commission's explanation that this correction is necessary as the authorisation was initially granted for 10 years although it contains a candidate for substitution. The BPR provides that these products can only be authorised for a maximum of 5 years. The authorisation holder was informed of this intended change.

Outcome of the vote by written procedure that took place between 25 October 2022 and 18 November 2022: favourable opinion

Section C Drafts presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Decision not approving cyanamide as an active substance for use in biocidal products of product types 3 and 18 (*SCBP77-Doc.C.01*)

The Commission introduced the item and reminded the SCBP members of the past discussions. In line with the agreement of the previous meeting, the Commission shared a letter by the applicant on cyanamide. A meeting will be held with the applicant, Commission, ECHA and evaluating Competent Authority. SCBP members will be expected to vote on the non-approval of cyanamide through written procedure in December. No comments were received from the SCBP members.

C.02 Exchange of views of the Committee on a draft Commission Implementing Decision not approving DBNPA as an active substance for use in biocidal products of product type 4 (*SCBP77-Doc.C.02*)

The Commission introduced the item and reminded the SCBP members of the past discussions. In line with the agreement of the previous meeting, the Commission drafted a proposal for non-approval considering that the conditions for derogation to exclusion set in Article 5(2) of the BPR are not met.

A Member State marked an editorial revision to a specific recital of the draft non-approval and Commission will reflect on it. SCBP members will be expected to vote on the non-approval of DBNPA through written procedure in December.

C.03 Exchange of views of the Committee on a draft Commission Implementing Decision not approving of certain active substances in biocidal products pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council (SCBP77-Doc.C.03)

The Commission introduced the background of this item. No comments were received from the SCBP members.

- **C.04** Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Icon 10CS in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP77-Doc.C.04*)
- **C.05** Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Phenogen in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP77-Doc.C.05*)

The Commission informed Member States that item C.04 and C.05 will not be discussed, as internal discussions are still ongoing.

C.06 Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Aquasan in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP77-Doc.C.06*)

The Commission presented that the unresolved disagreement on the mutual recognition of the product A-Quasan. The unresolved disagreement referred to the Commission was raised by the Netherlands as, in their opinion, the use of the biocidal product corresponds to product-type 2

instead of product-type 3, as originally authorised in Germany. As the active substance (benzoic acid) is not approved for that product-type, the Netherlands consider that the product does not meet the conditions of Article 19 (1) of the BPR. To sustain their position, the Netherlands refer to the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C)¹ ('the efficacy guidance') of the European Chemicals Agency which indicates in its chapters 5.4.2.3.1 and 5.4.3.1 that biocidal products applied for general disinfection of surfaces in the medical area (medical practices, hospitals) as well as of surfaces in veterinary practices associated with examination and operation/treatment of the animals are assigned to product-type 2, whereas products for specific veterinary hygiene purposes (e.g. products with specific claims against a target organism only relevant in the veterinary area) are considered to be in product-type-3. The efficacy guidance follows the agreement reached in May 2015 by the competent authorities of the Member States for the implementation of Regulation (EU) No 528/2012 and reflected in the document CA-May15-Doc8.3² ('the CA document').

Germany is of the opinion that the agreement presented in document CA-May15-Doc 8.3 does not make mandatory to assign biocidal products used for the disinfection of surfaces in the veterinary health care area exclusively to product-type 2. In their opinion, the document provides the possibility to assign, to product-type 2, biocidal products for general surface disinfection in veterinary health care area when the products are used in human and veterinary clinics, while the biocidal product at stake is not intended to be used in the human medical area.

After having carefully examined all the available information, the Commission concurs with the views of Germany that there is no impediment in Regulation (EU) No 528/2012, or in the document CA-May15-Doc8.3 for assigning the use of the biocidal products for disinfection of surfaces in the veterinary health care area to product-type 3. The efficacy guidance will be amended accordingly.

Member States were invited to provide comments on the draft decision by 31 October 2022.

- C.07 Exchange of views of the Committee on a Draft Commission Implementing Decision concerning the extension of the actions taken by the Health and Safety Executive of the United Kingdom permitting the making available on the market and use of the biocidal product Biobor JF in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council (SCBP77-Doc.C.07)
- C.08 Exchange of views of the Committee on a Draft Commission Implementing Decision concerning the extension of the actions taken by the competent authorities of several Member States permitting the making available on the market and use of the biocidal product Biobor JF in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council (SCBP77-Doc.C.08)

Items C.07 and C.08 were discussed together, as they concern decisions allowing the extension of temporary permits granted for the same product (Biobor JF). The Commission introduced the two draft acts, mentioning that the text is almost identical to that of the similar acts adopted

1

https://echa.europa.eu/documents/10162/23036412/bpr_guidance_assessment_evaluation_part_vol_ii_ part_bc_en.pdf/950efefa-f2bf-0b4a-a3fd-41c86daae468

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so far, with the exception of the justification in recital 3. Reference is no longer made in that recital to the immobility of aircraft, which is a factor aggravating the microbiological contamination of aircraft fuel tanks and fuel systems, but it is mentioned that the product is needed to control the contamination which can develop in the tanks and fuel systems (as such contamination can develop in both in-service and grounded aircraft). With regard to the decision addressed to several Member States, one Member State asked whether the act would be published before the end of October (when the national permit expires). The Commission indicated it is unlikely that the act is published before that date, but hopefully it will be soon after.

The Commission indicated that the drafts would be submitted to the vote of the Committee by written procedure as early as possible after the meeting.

Outcome of the vote by written procedure that took place between 25 October and 18 November 2022: favourable opinion

Section D <u>Any other business</u>

D.01 Union authorisation case discussed at BPC meeting in June 2022

One Member State made reference to one Union authorisation case concerning a biocidal products family consisting of disinfectant products, discussed at the BPC meeting of June 2022, for which this Member State submitted a minority opinion related to one of the uses of the products and the claims associated with this use (efficacy against enveloped viruses, but not also against non-enveloped viruses, which actually cause many food-borne diseases). In the view of this Member State, the authorisation of this use would lead to a lower food safety level. This Member State wanted to know whether the Commission analysed this minority opinion.

ECHA explained that at the efficacy working group meeting where the case was discussed, it was considered that if the product is efficacious against enveloped viruses, then it is also efficacious against non-enveloped viruses. ECHA will however check if this assumption is backed by evidence.

D.02 Information on Court ruling

The Commission informed about a judgement of the EU General Court concerning an access to documents request.