

7 Years after: Joining the Existing Joint Submission One Substance, One Registration

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- Preparation of registration of carbon black, difficulties with testing in Russia, search of laboratories
- Interaction with the CB4 Consortium, search for a compromise
- Collaboration with Russian and foreign carbon black manufacturers
- Communication with ECHA, the study of the Regulation
- Complete Opt-out
- ECHA requests on carbon black and additional testing
- New ECHA requirements on accession to the joint registration
- Resumption of negotiations with the Consortium and ECHA
- Joint registration of carbon black

Preparation of registration of carbon black, difficulties with testing in Russia, search of laboratories



- Carbon black; CAS 1333-86-4, EINECS 215-609-9 *in Annex VI of EC № 1272 (Classification, Labelling and Packaging Regulation)* required self-classification
- *Comparison of proposals of analytical laboratories for testing of carbon black according the REACH requirements*

№		Certificate	Scope of analysis	REACH report	Sampling	Cost (Rub.)
1	Health and Safety Laboratory	+	Only PAH	+	-	120 000
2	IOM Consulting	+	Only PAH	+	-	2 900
3	Dekra	+	+	+	-	54 640
4	Laus	+	+	+	-	223 000
5	Aqura	+	+	+	-	79 600
6	Eaglabs	+	Except PAH	+	-	31 200
7	CNRS/SCA	+	Except PAH	+	-	16 796
8	INERIS	+	Except PAH	+	-	51 600
9	IFP	+	Except PAH	+	-	34 160
10	SGS Vostok	+	Except PAH	+	+	78 000

Consortium Members

The following companies are members of the CB4REACH Consortium

2010

Cabot Corporation
Cancarb Limited.
Columbian Chemicals
Continental Carbon Company
EVONIK Degussa GmbH
Sid Richardson Carbon & Energy Company
Timcal Belgium S.A.

2017

Cabot Corporation
Cancarb Limited.
Columbian Chemicals
Continental Carbon Company
Orion Engineered Carbons GmbH
Sid Richardson Carbon & Energy Company
Imerys Graphite & Carbon Belgium S.A.

Substance

For this registration the definition Carbon Black covers products from various processes of which the most important are

Furnace Black

Thermal Black

Gas Black

Acetylene Black

Lamp Black

Channel Black

These are all included under CAS # 1333-86-4, EINECS # 215-609-9.

Interaction with the CB4 Consortium, quest for a compromise

- Letter of Access: Cost & Payment

Registration deadline	Tonnage band	Price (total)	1. payment	2. payment
2010	> 1000 t/y	180,000 €	single payment or see below	see below
2013	100 - 1000 t/y	65,000 €	single payment or see below	see below
2018	10 - 100 t/y	50,000€	no splitting if earlier payment	
2018	1 - 10 t/y	20,000 €	no splitting if earlier payment	

<http://www.cb4reach.eu/index.php?id=letterofaccesscosts>

- April 2009: Consortium announces that CB was successfully registered
- Three information letters from CB4 to SIEF (July, August and December 2009):
- Information that the dossier was submitted for registration, proposals for further cooperation on carbon black registration without specifying the cost of LoA.
- Properties of carbon black for identification. The requirement to confirm the intention to register a similar substance in SIEF until September 21, 2009.
- Request to registrants about the presence of heavy metals in CB
- March 2010 - information from the Consortium that the cost of the letter of access (token) will be 180 thousand Euros until 2018

- Meeting with CB4 (May 2010). Representatives of the Consortium put forward the following reasons for the high cost of the letter of access:
- (a) the dossiers includes several studies (including epidemiology), as they were separate parts of a large-scale study conducted in several countries;
- b) the research was conducted since the 1970s and a large amount of legal work was carried out, which also raised the price; (violates Article 30, paragraph 1 «Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements»)
- C) no proposals on the provision of own research results from other participants of the forum (SIEF), so only the Consortium data were used; (no request from the Consortium). 2,400 members were in the SIEF.
- d) in 2010, the Consortium received confirmation from 10 companies to register the substance, which set a precedent for allocation of the dossier value to the minimum number of participants.

- *Meeting of carbon black producers. Objectives and results:*
- *1. Exchange of the available information on registration of carbon black in accordance with the requirements of REACH.*
- *2. Possible actions and forms of cooperation to optimize risks and costs associated with registration.*
- *The participants decided:*
- *- to exchange of information about the carbon black SIEF and preparation for registration;*
- *- to continue discussion of the registration of carbon black.*
- *Participants: producers and importers of carbon black in Russia and Ukraine :*
- • *ООО Омсктехуглерод;*
- • *ОАО «Ярославский технический углерод» / ООО «Макрохим»*
- • *ОАО «Нижекамсктехуглерод»*
- • *ООО «Газпром экспорт»*
- • *ОАО «Ивановский техуглерод и резина»*
- • *ОАО «Туймазытехуглерод»*
- • *ОАО «Кременчугский техуглерод»*
- • *ООО «Конимпекс»*

Article 30 Sharing of data involving tests

1. Before testing is carried out in order to meet the information requirements for the purposes of registration, a SIEF participant shall inquire whether a relevant study is available by communicating within his SIEF. If a relevant study involving tests on vertebrate animals is available within the SIEF, a participant of that SIEF shall request that study. If a relevant study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study.

Within one month of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way. This may be facilitated by following any cost sharing guidance which is based on those principles and is adopted by the Agency in accordance with Article 77(2)(g). If they cannot reach such an agreement, the cost shall be shared equally.

Communication with ECHA, the study of the Regulation

- FAQs: 10.3. Can a registrant submit all the information specified in Article 10 (a) (iv), (vi), (vii) and (ix) separately?
- Registrants are allowed to submit the information specified in Article 10(a) (iv), (vi), (vii) or (ix) separately under the specific conditions listed in Article 11(3) of the REACH Regulation. Such an "opt out" can cover all information that the lead registrant submits on behalf of all member registrants, or it can cover only parts of this information.
- GUIDANCE ON PRE-REGISTRATION AND DATA SHARING:
- 8.4.1 What are the opt-out conditions from joint submission?
- As explained above, REACH requires the joint submission of studies, testing proposals and classification and labelling information. However, registrants are allowed to opt out from the joint submission under specific conditions (see below). It is important to note that opting out can be partial (i.e. for example a registrant may seek to protect confidential business information, or disagree with the Lead Registrant's selection of information, for a particular test, but otherwise use the dossier lodged by the Lead Registrant for all other shared information.)
- The right to opt out does not apply to the data sharing obligations, or to opting out of membership of the SIEF. Any exercise of the opt out must be fully justified in each case as prescribed by the REACH text.
- 8.4.2 What are the criteria to opt-out of joint submission?
- Paragraph 3 of Article 11 (and repeated in Article 19, which deals with joint submission of data for isolated intermediates) gives three allowed reasons for a registrant to opt out of joint submission:
- (1) it would be disproportionately costly for him to submit this information jointly; or
- (2) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or
- (3) he disagrees with the Lead Registrant on the selection of this information."
- Registrants invoking any or all of these conditions are required to "submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be." (Article 11, paragraph 3).

- July 2010: contract with the service provider
- Scope of work:
 - 1. The collection of data for the registration dossier (data sharing).
 - 2. Elaboration of a Chemical Safety Assessment (CSA) and preparation of a chemical safety report (CSR) in accordance with the requirements of REACH regulations.
 - 3. Elaboration of proposals for classification and labelling in accordance with EC Regulation No. 1272/2008 (CLP).
 - 4. Individual part of registration dossier (individual submission) in IUCUD5.2.
 - 5. Elaboration of safety data sheet (MSDS)
- 16.09.2010 certificate of registration

ECHA requests on carbon black and additional testing

- *Requests on:*
- *1. The content of hazardous substances in carbon black from the ECHA authorization list*
- *2. The presence of nanoparticles*
- *3. The presence of PAH (polyaromatic hydrocarbons)*
- *4. Compliance with the requirements of FDA (Food and Drug Administration)*
- *5. Compliance with the Food Contact legislation*
- *6. Compliance with the REACH requirements*
- *7. Conformity of carbon black for requirements of the food industry packaging*
- *8. Content of chlorine, Cetyltrimethylammonium Bromide, Polychlorinated naphthalene and N-phenyl-Benzanamine, toluene, cyclohexane and benzo [a] pyrene in carbon black (Purity criteria of carbon black),*
- *9. Use of mineral raw materials from Congo in the production of carbon black (tungsten, tin, gold)*
- *10. Full physico-chemical dossier for carbon black (23-page inquiry)*

March 27, 2017 REACH-IT message from ECHA :Concerning individual registrants, a failure to join the existing joint submission by 04/10/2017 would result in ECHA revoking its decision assigning a registration number to their registration and the rejection of this registration.

- In accordance with Articles 11(1) and 19(1) of the REACH Regulation, when a substance is intended to be manufactured or imported in the European Union by one or more manufacturers and/or importers, some of the information referred to in Articles 10 and 12 of the REACH Regulation must be submitted first by a lead registrant, acting with the agreement of the other assenting registrants. This requirement is re-affirmed by Article 3(1) of the Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing. Whilst remaining part of the joint submission for the same substance, registrants can 'opt-out' from the relevant parts of the joint submission under Articles 11(3) or 19(2) of REACH.
- If ECHA decides to revoke its decision assigning a registration number to the registration concerned and rejects this registration, the individual registrant concerned will have to cease importing or manufacturing the substance, unless they have a valid pre-registration and the quantities manufactured or imported per manufacturer or importer per year remain below 100 tonnes (see Articles 23(3) and 28(1) of REACH).

- *1. Question to ECHA about the mechanism of joining the Joint submission. (dossier update).*
- *2. Update the dossier in IUCLID. (select “Joint submission” in the process of completing the dossier, update the Chemical Safety Report, in REACH-IT is necessary to add the token received from the lead registrant).*
- *3. Negotiations with CB4 on the acquisition of a part of the dossier. For this:*
 - *(a) to request a list of tests and their price.*
 - *b) to identify missing tests (by CSR).*
 - *c) to offer CB4 to buy only part of information.*
 - *d) if we do not agree on the price, to start a milestone formal dispute procedure on get access to the information (free access).*

TOKEN Carbon Black

EC 215-609-9

CAS 1333-86-4

Joint submission name: Carbon Black

Joint Submission Security token: xxxxxxxxxxxxxxxxxxxxxxxx

Expiry date:

30/11/2017

Since we already have the ECHA-approved registration dossier, we decided to purchase a reference only to some of the studies that we lack in our dossier to fully comply with the joint registration.

1 March 2018. Decade of REACH dossier evaluation reveals 70% non-compliance. Over 2,500 Echa information requests made since 2008, approximately seven in ten have failed to be compliant (data gaps).

“One Substance, One Registration” (OSOR)

Article 11 Joint submission of data by multiple registrants. It is also referred to in the European Commission Implementing Regulation 2016/9, which states that entities registering a substance with the same EC number should be members of the same joint submission. 78 registrations within LOA are revised.

Some of the substance descriptors used by the LOA REACH Consortium were also used by CONCAWE. Though the compositions and manufacturing processes differ between the consortia (CONCAWE’s refinery-processes vs LOA’s steam-cracking processes), multiple joint submissions were created using the same EC name and EC number.

Thank you for your attention!

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