Digest of Decisions of the Board of Appeal of the European Chemicals Agency

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List of abbreviations

BoA	Board of Appeal
BPR	Biocidal Products Regulation, Regulation (EU) No 528/2012
CA	Competent Authority
CoRAP	Community Rolling Action Plan
EA	(anti)androgenic and (anti)estrogenic
ECHA	European Chemicals Agency
ECJ	Court of Justice
eMSCA	Evaluating Member State Competent Authority
EOGRTS	Extended One-Generation Reproductive Toxicity Study
GC	General Court
LAGDA	Larval Amphibian Growth and Development Assay
MAD	Mutual Acceptance of Data
MSC	Member State Committee
NGO	Non-Governmental Organisation
OECD TG	Test Guideline of the Organization for Economic Cooperation and Development
PBT	Persistent, bioaccumulative and toxic
PfA	Proposal for Amendment
PNDT	Pre-natal Developmental Toxicity
QSAR	Quantitative Structure-Activity Relationship
RAC	Risk Assessment Committee
RBoA	Registry of the Board of Appeal
RCR	Risk Characterisation Ratio
REACH	REACH Regulation, Regulation (EC) No 1907/2006
RMM	Risk Management Measures
RoP	Rules of Procedure of the Board of Appeal, Commission Reg. (EC) No 771/2008
SIEF	Substance Information Exchange Forum
SME	Small or medium-sized enterprise
TFEU	Treaty on the Functioning of the European Union
UVCB	Substance of Unknown or Variable composition, Complex reaction product or Biological material
vPvB	Very persistent and very bioaccumulative
WoE	Weight of Evidence

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1. SCOPE AND INTENSITY OF REVIEW, POWERS OF THE BOA

1.1. Scope of review

General. When examining the merits of a case, the BoA confines itself, in principle, to examining whether the pleas put forward by an appellant demonstrate that the contested decision is vitiated by an error. (Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 68; Decision of 23.02.2021, Joined Cases A-016-2019 to A-029-2019, *Lubrizol France and others*, para. 103)

An appellant cannot simply claim that the result of the assessment on which a contested decision is based should have been different, but must put forward arguments to show the existence of errors vitiating the scientific assessment on which the contested decision is based. (Decision of 23.02.2021, Joined Cases A-016-2019 to A-029-2019, *Lubrizol France and others*, para. 104; Decision of 07.09.2021, A-008-2020, *Sustainability Support Service (Europe)*, para. 54; Decision of 14.12.2021, A-007-2021, *Global Product Compliance (Europe)*, para. 39)

The BoA is not limited to assessing whether the Contested Decision contains errors of assessment which are manifest. (Decision of 23.08.2022, Case A-004-2021, *Celanese Production Germany*, para. 36 quoting judgment of 20 September 2019 in case T-125/17, *BASF Grenzach* v *ECHA*, EU:T:2019:638, para. 89)

The procedure before the BoA is adversarial in nature. The subject of a case before the BoA is determined by the grounds of appeal put forward by the appellant. (Decision of 07.09.2021, A-008-2020, *Sustainability Support Service (Europe)*, para. 26)

De novo review. The BoA can carry out a new, full examination as to the merits of the appeal, in terms of both law and fact. (Decision of 10.10.2011, Case A-001-2010, *EPZ*, para. 36-38) [*Obsolete following the subsequent judgment of 20 September 2019 in BASF Grenzach v ECHA, T-125/17, EU:T:2019:638, para. 59-60, according to which the Board of Appeal is not to conduct a de novo review but to confine itself to examining whether the arguments put forward by the applicant are such as to demonstrate the existence of an error vitiating the contested decision]*

1.2. Intensity of review

General. The intensity of the BoA's review of the use made by ECHA of administrative discretion goes beyond finding whether a measure is manifestly inappropriate to achieve the objective pursued. (Decision of 19.06.2013, Case A-005-2011, *Honeywell Belgium*, para. 117)

According to the EU Courts, the legality of a measure contested before it and adopted in a sphere of broad administrative discretion can be affected only if the measure is manifestly inappropriate having regard to the objective which the legislature is seeking to pursue. However, in relation to the 'manifestly inappropriate' criterion set by the EU Courts when conducting a judicial review of the proportionality of a measure, the BoA underlines the clear differences between itself and the EU Courts. In particular, the latter refrain from substituting their own assessment for that of the EU institution whose decision is being reviewed. However, under Article 93(3) REACH, the BoA 'may exercise any power which lies within the competence of the Agency […]'. Thus, the BoA can inter alia replace a decision under appeal with a different decision. Moreover, in conducting its administrative review of ECHA decisions, the BoA possesses certain technical and scientific expertise which allows it to enter further into the technical assessment made by ECHA than would be possible by the EU Courts. As a result, when examining whether a decision adopted by ECHA is proportionate, the BoA considers that it should not be limited by the need to establish that the decision is 'manifestly inappropriate' to the objective pursued. (Decision of 19.06.2013, Case A-005-2011, *Honeywell Belgium*, para. 116-118; Decision of 23.09.2015, Case A-005-2014, *Akzo Nobel and Others*, para. 53-54)

Difference of scientific opinion. A mere difference in scientific opinion does not suffice to establish that a decision is vitiated by error. (Decision of 07.10.2016, Case A-017-2014, *BASF*, para. 77-78; Decision of 30.06.2017, Case A-014-2015, *Grace*, para. 121; Decision of 30.06.2017, Case A-015-2015, *Evonik Degussa*, para. 174; Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 54; Decision of 27.10.2015,

Case A-006-2014, *International Flavors & Fragrances*, para. 102; Decision of 19.12.2016, Case A-018-2014, *BASF*, para. 133-134; Decision of 09.02.2021, Case A-015-2019, *Polynt*, para. 72-73)

1.3. Powers of the BoA if an appeal is well-founded

General. Under Article 93(3) REACH, following its examination of a case, the BoA may exercise any power that lies within the competence of ECHA or remit the case to the competent body of ECHA for further action. That provision governs solely the BoA's powers after having held that an action before it was well founded. (Decision of 22.06.2021, *Tecnofluid*, Case A-002-2020, para. 58)

If an appeal is unfounded, the BoA has no power to alter the operative part of a contested decision. (Decision of 23.08.2022, Case A-004-2021, *Celanese Production Germany*, para. 166)

Article 93(3) REACH does not empower the BoA to take a decision that would go beyond the scope of the decision of ECHA that is contested before it. Article 93(3) REACH must be read in conjunction with the provision on which a contested decision is based. If – as in the present case – a contested decision is based on Article 30(3) REACH, the BoA may only exercise the powers that ECHA has under that provision. (Decision of 23.07.2020, Joined Cases A-013-2018 to A-024-2018, *Tecnofluid*, para. 31-33)

The BoA has no power to instruct ECHA to initiate a specific procedure or to give instructions to registrants, in that case a request to initiate a relevant procedure against the Intervener for breaches of Article 25 REACH. (Decision of 05.02.2020, Case A-022-2018, *Sustainability Support Service (Europe)*, para. 20)

Replacement of evaluation decisions. Before replacing a decision with its own decision, the BoA must examine whether the available evidence allows it to do so. In addition, when examining whether it can replace an ECHA decision, the BoA must bear in mind the procedure for adopting ECHA decisions under the substance evaluation process set out in Articles 50 to 52 REACH, and in particular the role of the various actors in that procedure. (Decision of 29.01.2020, Case A-008-2018, *Taminco and Performance Additives Italy*, para. 93 and 101; Decision of 10.05.2021, Case A-002-2021, *Lanxess Deutschland and Schirm*, para. 109 quoting judgment of 20.09.2019 in case T-125/17, *BASF Grenzach* v *ECHA*, EU:T:2019:638, para. 118)

> ***Illustration***. A contested substance evaluation decision was partially annulled (i.e. modified) insofar as it implied that the addressees were required to perform tests on composition other than those which they have registered. (Decision of 12.07.2016, Case A-009-2014, *Albemarle Europe*, para. 131 and 134)
>
> ***Illustration***. A contested compliance check decision was partially annulled insofar as it required the inclusion of additional investigations on learning and memory function in an EOGRTS, but confirmed for the remainder. (Decision of 25 April 2023, Joined Cases A-002-2022 and A-003-2022, *BASF Lampertheim and Metall-Chemie*, para. 65-67; Decision of 19.09.2022, Case A-009-2022, *Nouryon Functional Chemicals and Others*, para. 139-142 [decision currently subject to appeal before the General Court])

Replacement of data-sharing decisions. In data-sharing cases, the BoA has replaced a contested decision with a different decision (Decision of 23.07.2020, Case A-013-2018, Tecnofluid, para. 56 to 59) or ordered ECHA to adopt a decision with a specific content. (Decision of 23.07.2020, Joined Cases A-014-2018 to A-021-2018, *Tecnofluid*, para. 97-99)

Substitution of the reasons. In a decision concerning a compliance check the BoA replaced the reasoning in the contested decision with a different reasoning and rejected the appeal. (Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 177-181)

Severability. The appellants requested the partial annulment of the contested decisions in so far as they referred to the terms 'grades', 'forms' and 'nanoforms'. However, those terms were an integral part of the reasoning for the requested information, and inseparable from the

content of the contested decision. The BoA was unable to simply remove those terms from the contested decisions and to order the appellant to comply with the remainder of the contested decisions. Therefore, the BoA annulled the contested decisions in their entirety. (Decision of 12.10.2016, Case A-008-2015, *Evonik Degussa*, para. 61-62; Decision of 12.10.2016, Case A-009-2015, *Iqesil*, para. 61-62; Decision of 12.10.2016, Case A-010-2015, *Rhodia*, para. 61-62; Decision of 12.10.2016, Case A-011-2015, *J.M. Huber Finland*, para. 61-62)

2. ADMISSIBILITY OF APPEALS

2.1. General

General. Pursuant to Article 6(1)(d) RoP, the notice of appeal must contain the remedy sought by the appellant. Moreover, under Article 12(2) RoP, no new plea in law, and a fortiori no new form of order, may be introduced after the first exchange of written pleadings unless it is based on new matters of law or of fact that come to light in the course of the proceedings. (Decision of 19.12.2016, Case A-018-2014, *BASF*, para. 31-32; Decision of 14.02.2023, Case A-012-2021, *Covestro*, para. 61)

Appeal submitted by several appellants. Where the same appeal is involved, and it is found that the bringing of the appeal by one appellant is admissible, there is no need to consider whether the other appellants are entitled to bring proceedings. (Decision of 02.03.2017, Case A-011-2014, *Huntsman P&A UK*, para. 28; Decision of 06.08.2018, *SI Group UK and Others*, Case A-006-2016, para. 29)

Incorrect statement of remedies. The competence of the BoA, as set out in the REACH Regulation, cannot be altered by an incorrect statement of remedy in a decision of ECHA. (Decision 23.03.2018, Case A-011-2017, *REACheck Solutions*, para. 66)

2.2. Challengeable acts

2.2.1. Acts which may be reviewed by the BoA

Completeness check decisions. Any ECHA decision taken under Article 20 REACH may be appealed in accordance with Article 91(1) REACH, despite the more limited wording of Article 20(5) REACH. (Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 62)

Preparatory acts. Although a preparatory act cannot be the subject of an appeal, legal defects in a preparatory act may be relied upon in an appeal directed against the definitive decision. (Decision of 04.04.2019, Case A-013-2017, *SwissInno Solutions (Peanut butter)*, para. 45; Decision of 04.04.2019, Case A-014-2017, *SwissInno Solutions (Brandy)*, para. 45)

> ***Illustration***. Defects in a decision on an initial declaration of interest to notify food substances for inclusion in the BPR Review Programme affected the legality of the contested decision rejecting the notification that followed the declaration of interest to notify. (Decision of 04.04.2019, Case A-013-2017, *SwissInno Solutions (Peanut butter)*, para. 41 and 46; Decision of 04.04.2019, Case A-014-2017, *SwissInno Solutions (Brandy)*, para. 41 and 46)

SME verification decisions. SME Decisions are taken by the ECHA as a constitutive part of the completeness check procedure and, as such, subject to the jurisdiction of the BoA. Administrative processes such as the separation of technical completeness and 'financial completeness' checks, set up for the purpose of administrative convenience, must not alter the system of remedies set out in the REACH Regulation. (Decision of 21.05.2014, Case A-002-2013, *Distillerie De la Tour*, para. 51 and 54-55) *[Obsolete following the subsequent judgment of 15 September 2016, Crosfield Italia v ECHA, T-587/14, EU:T:2016:475, para. 18-23, according to which an SME verification decision adopted by ECHA fell within the jurisdiction of the General Court]*

Statement of non-compliance (SONC). A statement of non-compliance examining new and substantial information is equivalent to a decision taken under Article 42 REACH and can therefore be appealed before the BoA. (Decision of 29.07.2015, Case A-019-2013, *Solutia Europe, para. 93-98*) *[Obsolete following the subsequent judgment of 8 May 2018, Esso Raffinage v ECHA, T-283/15, EU:T:2018:263, para. 34-37, according to which ECHA's statement of non-compliance fell within the jurisdiction of the General Court, see also* Decision of 16.09.2019, Case A-012-2019, *Symrise* and Decision of 16.09.2019, Case A-013-2019, *Symrise]*

2.2.2. Acts which may not be reviewed by the BoA

General. The Board of Appeal is competent to examine only those acts which are formally adopted on the basis of one of the provisions referred to in Article 91(1) (Decision of 17.01.2023, Case A-012-2022, *International Flavors & Fragrances*, para. 7, 11)

Decision granting a 'token' in case of a complete opt-out. A decision granting a 'token' to a registrant relying on a complete opt-out, and therefore allowing that registrant to submit its registration dossier as part of the joint registration, is based on Article 11 REACH. Article 11 REACH is not listed in Article 91(1) REACH among the decisions that can be challenged before the BoA. (Decision 23.03.2018, Case A-011-2017, *REACheck Solutions*, para 59 to 66)

Permission to continue manufacturing. The responsibility to verify whether companies have complied with the provisions of the REACH Regulation regarding the registration of the substances they manufacture or import falls within the competence of the Member States. As a result, neither ECHA nor the BoA is competent to decide whether a registrant which has submitted a registration dossier for a phase-in substance by the deadline set in Article 23 REACH, has failed the completeness check under the third subparagraph of Article 20(2) REACH, and has not yet received a registration number pursuant to Article 20(3) REACH, is permitted to continue manufacturing or importing a particular substance until a registration number is assigned by ECHA. (Decision of 03.12.2014, Case A-005-2013, *Vanadium* (I), para. 63)

Failure to act. The BoA does not have competence to examine claims concerning ECHA's failure to act. (Decision of 25.09.2015, Case A-019-2015, *Lysoform and Others*, para. 35; Decision of 25.09.2015, Case A-020-2015, *Lysoform and Others*, para. 35)

Community Rolling Action Plan (CoRAP). The BoA is not competent to decide on appeals against an ECHA decision to include a substance on the CoRAP. (Decision of 30.06.2017, Case A-015-2015, *Evonik Degussa,* para. 66)

Member States' compliance with international law. The BoA is not competent to determine whether Member State Competent Authorities breached their obligations under international law. (Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum*, para. 107)

BoA RoP. The BoA is not competent to decide on the legality of the RoP, which are a Commission regulation. (Decision of 06.08.2018, *SI Group UK and Others*, Case A-006-2016, para. 202)

Legality of the Test Methods Regulation. The BoA is not competent to decide on the legality of the Test Methods Regulation, which is a Commission Regulation (Decision 06.06.2018, Case A-006-2016, *SI Group UK and Others*, para. 202; Decision of 10.05.2021, Case A-002-2021, *Lanxess Deutschland and Schirm*, para. 79)

SME verification decisions. An SME verification decision has its legal basis in Article 13(4) REACH Fee Regulation No 340/2008 and Article 4 of Management Board Decision MB/D/29/2010. Acts adopted on the basis of those provisions do not fall within the competence of the BoA. (Decision of 05.07.2019, Case A-008-2019, *Cocotama Germany,* para. 9-10)

Follow-up communication to a national enforcement authority (NEA). A communication to a NEA and entitled 'Information of a failure to respond to a dossier evaluation decision' is not adopted on the basis of any of the Articles listed in Article 91(1) REACH and, as such, the BoA is not competent to decide on an appeal against such communication. The General Court has declared itself competent to decide on actions against such communications. (Decision of 16.09.2019, Case A-012-2019, *Symrise,* para. 24-29; Decision of 16.09.2019, Case A-013-2019, *Symrise,* para. 25-30)

Opinions of the biocidal Products Committee (BPC). A BPC opinion adopted pursuant to Article 89(1) BPR and Article 7(2) of Commission Delegated Regulation (EU) No 1062/2014 on the work programme is not one of the types of acts that fall within the competence of the BoA,

nor does it bear any relation to any of those types of acts. (Decision of 02.09.2019, Case A-011-2019, *Sikma D,* para. 4-5)

'Assessment of Regulatory Needs' (ARN). An ARN, which is a document identifying concerns and mapping out future regulatory measures, does not fall within the competence of the BoA. (Decision of 17.01.2023, Case A-012-2022, *International Flavors & Fragrances*, para. 8)

2.2.3. Acts which are purely confirmatory of a previous decision

General. A measure is regarded as merely confirmatory of a previous decision if it contains no new factor as compared with the previous measure and was not preceded by a re-examination of the circumstances of the person to whom that measure was addressed. However, the confirmatory or other nature of a measure cannot be determined solely with reference to its content as compared with that of the previous decision which it confirms. The nature of the contested measure must also be appraised in the light of the nature of the request to which it constitutes a reply. In particular, if the measure constitutes the reply to a request in which substantial new facts are relied on, and whereby the administration is requested to reconsider its previous decision, that measure cannot be regarded as merely confirmatory in nature, since it constitutes a decision taken on the basis of those facts and thus contains a new factor as compared with the previous decision. In the case-law of the EU courts, facts are considered new if neither the applicant nor the administration could have had prior knowledge of them. Information is considered substantial if it is capable of substantially altering the applicant's legal situation from that which prevailed when the earlier decision was adopted. (Decision of 29.07.2015, Case A-019-2013, *Solutia Europe*, para. 77-79)

2.3. Standing to bring an appeal

2.3.1. Legal interest

General. An appeal brought by a natural or legal person is admissible only in so far as that person has an interest in the annulment of the contested decision. An appellant's interest in bringing proceedings must, having regard to the purpose of the action, exist at the stage of lodging the appeal, failing which the action will be inadmissible. In addition, the interest in bringing proceedings must continue until the final decision. Failing this there will be no need to adjudicate, which presupposes that the appeal must be likely, if successful, to procure an advantage for the appellant. If an appellant's interest in bringing proceedings disappears in the course of those proceedings a decision on the merits cannot bring it any benefit. (Decision of 29.07.2015, Case A-019-2013, *Solutia Europe*, para. 38-41)

As a matter of principle, an appellant can still have a legal interest in bringing an appeal against a decision, even if the decision has been complied with. However, the annulment of the decision must have legal consequences which would benefit the appellant. (Decision of 29.07.2015, Case A-019-2013, *Solutia Europe*, para. 42)

An appellant has an interest in challenging a decision requesting to limit a registration dossier to a 'pure' compound, with the exclusion of a separate 'mixture' compound, even if it accepted ECHA's request because this acceptance was made conditional on the understanding that no separation registration for the 'mixture' was necessary. (Decision of 02.04.2014, Case A-008-2012, *PPH Utex*, para. 23-24)

Follow-up decision. Under the follow-up procedure under Article 42 REACH, an appellant has an interest in the annulment of an ECHA decision requiring the submission of additional information as he would be running a significant risk in not carrying out the requested studies because ECHA may reject a waiving strategy, which may result in enforcement action. (Decision of 01.08.2013, Case A-003-2012, *Thor*, para. 56)

2.3.2. Direct and individual concern

2.3.2.1. General

EU case law as a guide for interpretation. In interpreting the concept of 'direct and individual concern' in Article 92(1) REACH, the BoA must be guided by the settled case law of the ECJ. On this basis, the contested act must directly affect the legal situation of an applicant and leave no discretion to the authorities responsible for implementing that act, such implementation being purely automatic and resulting from EU law alone, without the application of other intermediate rules. (Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 69 and 83; Decision of 30.05.2017, Case A-022-2015, *Michelin*, para. 116)

The BoA cannot give a 'flexible' or 'inclusive' interpretation of the admissibility requirements set out in Article 92(1) REACH. Whilst the Lisbon Treaty introduced the possibility for applicants to challenge regulatory acts which are of direct concern to them and do not entail implementing measures, it has not affected the definition of direct and individual concern. In any event, the contested decision in the case was not a regulatory act but a decision addressed to registrants of the substance. (Decision of 30.05.2017, Case A-022-2015, *Michelin*, para. 115)

Cumulative criteria. Direct and individual concern are cumulative requirements. (Decision of 30.05.2017, Case A-022-2015, *Michelin*, para. 117)

Breach of procedural rights. Should the substance evaluation procedure include procedural rights for the downstream users which were not taken into account in the procedure leading to the adoption of the contested decision, this circumstance on its own would provide to the appellant legal standing to challenge a decision that affects its procedural rights. (Decision of 30.05.2017, A-022-2015, *Michelin*, para. 42)

2.3.2.2. Direct concern

General. The contested act must directly affect the legal situation of an applicant and leave no discretion to the authorities responsible for implementing that act, such implementation being purely automatic and resulting from EU law alone, without the application of other intermediate rules. (Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 83)

Completeness check decision addressed to another registrant of the same substance. As it was uncontested that the appellant is the 'sole owner of rights to the study results' relevant to the registration of the substance and contained in the lead registrant's dossier, including studies conducted on vertebrate animals, the contested decision affected the appellant's legal position by allowing another registrant to register the substance outside the joint submission, and therefore enabling it to circumvent its obligations as a joint registrant with regard to data- and cost-sharing. Furthermore, the appellant was itself subject to obligations under Articles 11 and 27 REACH, following an inquiry of the other registrant. (Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 86 and 87)

Completeness check decision. An ECHA decision confirming the completeness of a registration dossier does not require any implementation. (Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 86 and 88)

Relevant moment in time. The admissibility requirement of individual concern must be met at the time the contested measure was adopted. The BoA considers that the same principle has to be applied in relation to direct concern. Any contrary interpretation would infringe the requirements of legal certainty and the need to avoid all discrimination or arbitrary treatment in the administration of justice (Decision of 30.05.2017, A-022-2015, *Michelin*, para. 140)

On direct concern in case of an appellant challenging a substance evaluation decision as (1) downstream user, (2) SIEF member, (3) member of a SIEF agreement, (4) new consortium member and (5) company joining a consortium after the adoption of the contested decision. (Decision of 30.05.2017, A-022-2015, *Michelin*, para. 123-129, 130-136, 142-146 and 147-149, respectively)

2.3.2.3. Individual concern

General. Persons other than those to whom a decision is addressed may only claim to be individually concerned if that decision affects them by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and by virtue of these factors distinguishes them individually just as in the case of the person addressed. Moreover, where a contested measure affects a group of persons who were identified or identifiable when that measure was adopted by reason of criteria specific to the members of the group, those persons might be individually concerned by that measure inasmuch as they form part of a limited class of traders. (Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 91)

Completeness check decision addressed to another registrant of the same substance. As the lead registrant for the substance and the 'sole owner of rights to the study results' relevant to the registration of the substance, including tests involving vertebrate animals, the appellant had a particular interest in ensuring that the other registrants of the Substance fulfil their obligations under Articles 11 and 27 REACH. The contested decision deprived the appellant of the possibility to share the cost of data obtained through testing on vertebrate animals with the other registrant. As a result, the contested decision was of individual concern to the appellant. (Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 94)

2.4. Time-limit for filing an appeal

General. The time-limit for bringing an appeal is a matter of public policy. The BoA must ascertain of its own motion whether it was observed. (Decision of 27.02.2013, *SEI EPC ITALIA*, Case A-005-2012, para. 22; Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 48)

In order to be able to prove the date on which the notification of a decision is received by the appellant, and therefore the date on which the time limit for lodging an appeal starts to run, ECHA ought to request registrants to confirm the receipt of e-mails or request a receipt from the REACH-IT system. (Decision of 27.02.2013, Case A-005-2012, *SEI EPC Italia*, para. 28-29 and 31)

Excusable error. It is the responsibility of every REACH-IT account holder to update the information concerning its user account details, so as to ensure that communications are addressed to the appropriate contact person. (Decision of 27.02.2013, Case A-005-2012, *SEI EPC Italia*, para. 34; Decision of 13.11.2014, Case A-020-2013, *Ullrich Biodiesel*, para. 32)

This also applies to registrants during the procedure leading to the adoption of a decision. (Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 130)

Human errors cannot be regarded as exceptional and unforeseeable events and therefore such errors constitute a failure to comply with the obligation to exercise due care. The concept of excusable error, which must be strictly construed, can concern only exceptional circumstances in which, in particular, the conduct of the institution concerned has been, either alone or to a decisive extent, such as to give rise to a pardonable confusion in the mind of a party acting in good faith and exercising all the diligence required of a normally experienced trader. (Decision of 13.11.2014, Case A-020-2013, *Ullrich Biodiesel*, para. 32-34)

2.5. Absence of pleas in law, form of order

Absence of pleas in law. An appeal may be declared inadmissible if the appellant does not set out in a comprehensible manner the grounds of its appeal, that is to say the pleas in law and the arguments of fact or law on which it relies. (Decision of 07.10.2011, Case A-004-2011, *Kronochem*, para. 47; Decision of 07.09.2021, A-008-2020, *Sustainability Support Service (Europe)*, para. 23-28; Decision of 14.12.2021, A-007-2021, *Global Product Compliance (Europe)*, para. 23; Decision of 28.02.2023, Case A-013-2021, *Gruberchem*, para. 20; Decision of 28.02.2023, Case A-014-2021, *Gruberchem*, para. 20)

The pleas must be contained in the notice of appeal. A plea which is raised later in the proceedings cannot remedy the initial inadmissibility of an appeal. (Decision of 28.02.2023, Case A-013-2021, *Gruberchem*, para. 20; Decision of 28.02.2023, Case A-014-2021, *Gruberchem*, para. 20)

An appeal is not inadmissible if the facts and the contested decision are identified, however briefly, with sufficient precision to enable the BoA to examine the appeal and ECHA to present a defence, albeit on the assumption that the decision is being contested in its entirety. The degree of precision and detail required in the notice of appeal are dependent upon the circumstances of the case, inter alia its complexity. (Decision of 07.10.2011, Case A-004-2011, *Kronochem*, para. 31 and 50)

If the notice of appeal contains pleas and arguments which are set out in a comprehensible manner, the admissibility and substantive merit of those pleas and arguments are a question concerning the substance of the appeal, not its admissibility. (Decision of 28.02.2023, Case A-013-2021, *Gruberchem*, para. 23; Decision of 28.02.2023, Case A-014-2021, *Gruberchem*, para. 23)

Absence of form of order. Where the appellant has not explicitly requested remedies, it may nonetheless be possible to infer a particular form of order sought from the notice of appeal read as a whole. (Decision of 01.08.2013, Case A-003-2012, *Thor*, para. 45)

Supplementing the notice of appeal. An appeal is not inadmissible on the grounds that no pleas in law are contained in the notice of appeal, provided that that notice is supplemented by such pleas within the time limit prescribed for the lodging of an appeal. (Decision of 07.10.2011, Case A-004-2011, *Kronochem*, para. 38, 40 and 42)

Requirements for the form of order (lack of precision). Article 6(1)(d) of the Rules of Procedure provides that the notice of appeal must contain the remedy sought by the appellant. The remedy sought defines the scope of the dispute and must be set out clearly in the notice of appeal. However, a lack of precision in that regard does not lead to inadmissibility if the remedy sought can be discerned from the entirety of the arguments put forward by the party in question. (Decision of 19.09.2023, Case A-009-2022, *Nouryon Functional Chemicals and Others*, para. 21 [currently subject to appeal before the General Court])

3. ADMISSIBILITY OF PLEAS IN LAW AND EVIDENCE

3.1. General

General. Only arguments specifically made in a submission for the case at issue can be considered by the BoA. References to arguments made in other cases, unless reiterated in full, cannot be accepted. (Intervention Decision of 12.02.2016, Case A-014-2015, *Grace (ClientEarth and CIEL)*, para. 16; Intervention Decision of 10.02.2016, Case A-015-2015, *Evonik Degussa (ClientEarth and CIEL)*, para. 19)

ECHA submitted its observations on admissibility within the time-limit set for the defence and in the proper form. This submission and ECHA's claims concerning the admissibility of the appeal were therefore examined by the BoA. However, the BoA did not examine ECHA's substantive arguments that were lodged after the deadline set for the defence and the interveners substantive arguments in the statement in intervention. (Decision of 30.05.2017, Case A-022-2015, *Michelin*, para. 66)

3.2. Late pleas in law

New pleas in law. New pleas are inadmissible unless they are based on new matters of law and fact which come to light in the course of the proceedings. (Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 144 ff.; see also Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 32; Decision of 07.09.2021, A-008-2020, *Sustainability Support Service (Europe)*, para. 36; Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 31; decision of 29.08.2023, Case A-006-2022, *Symrise and Others*, para. 26)

> ***Illustration***. The contested decision consisted of three separate decisions and the BoA examined its competence in relation to the pleas raised against each of the three. For one of the 'decisions' (access to the joint submission), the BoA observed that it was not a decision that could be appealed before the BoA. For another of the 'decisions' (providing additional time to the data claimant to submit its registration dossier), the BoA noted that the appellant (a previous registrant) was not an addressee of the decision (but only in copy), and that the appellant had not established that it was directly concerned by the decision. (Decision of 27.10.2020, A-024-2018, *Symrise*, para 31-32, 38-43, 49-59)

New arguments in support of previously made pleas. A novel legal argument supporting a plea already made in the notice of appeal does not constitute a new plea in law. (Decision of 10.10.2011, Case A-001-2010, *EPZ*, para. 86)

A new and unsubstantiated argument cannot be used to call into question ECHA's assessment during the decision-making process. (Decision of 01.08.2016, Case A-014-2014, *BASF Pigment*, para. 38; Decision 01.08.2016, Case A-003-2015, *BASF Pigments*, para. 45)

New pleas in law which can be regarded as amplifying or developing a plea made previously, whether directly or by implication, are admissible. (Decision of 19.06.2013, Case A-005-2011, *Honeywell Belgium*, para. 61)

Enlargement of the scope of the appeal. The appellant may not enlarge the scope of the appeal by contesting additional aspects of a decision at a later stage of proceedings if he has not done so before the expiry of the deadline for submitting an appeal. If the appellant initially challenges a decision not to take into account a dossier update, a subsequent request for examining the adequacy of the information provided in the dossier update would qualify as scope enlargement. (Decision of 01.08.2013, Case A-003-2012, *Thor*, para. 65-66)

3.3. Pleas of public policy

According to settled case-law, in an action for annulment the European Union Courts may – or even must – raise pleas of their own motion if they concern a matter of public policy. Rules concerning the competence of the author of an act are such a matter of public policy. That

case-law applies by analogy to proceedings before the Board of Appeal. (Decision of 28.02.2023, Case A-013-2021, *Gruberchem*, para. 26-27; Decision of 28.02.2023, Case A-014-2021, *Gruberchem*, para. 26-27)

3.4. Pleas directed against other acts than the Contested Decision

The Appellant's pleas are based, in essence, on the argument that the Appellant is a small enterprise within the meaning of Commission Recommendation 2003/361/EC. This argument was addressed and rejected in the SME verification decision of 3 December 2020. However, the considerations that are addressed in the SME verification decision of 3 December 2020 are also part of the Contested Decision, which is based on the Appellant's failure to pay the top-up fee imposed with the SME verification decision of 3 December 2020. The SME verification decision of 3 December 2020 informs the Contested Decision. As the Board of Appeal is competent to decide on the Contested Decision, and the Contested Decision is based inter alia on the Appellant's company size, the Board of Appeal is also competent to decide on the Appellant's pleas. Those pleas are therefore admissible. Nevertheless, the Board of Appeal is bound by the findings of the SME verification decision of 3 December 2020, which has not been challenged before the General Court and is therefore final. The Board of Appeal cannot depart from the findings of the SME verification decision of 3 December 2020. Therefore, the Appellant's pleas cannot bring about the annulment of the Contested Decision. (Decision of 28.02.2023, Case A-013-2021, *Gruberchem*, para. 104-108; Decision of 28.02.2023, Case A-014-2021, *Gruberchem*, para. 104-108)

3.5. Late evidence

General. Article 12(1) RoP provides that no further evidence may be introduced after the first exchange of written pleadings unless the BoA decides that the delay in offering the evidence is duly justified. A delay in offering evidence is justified where, for example, it is presented to support arguments offered to rebut arguments raised for the first time in the defence or where the evidence in question was in preparation at the time of the deadline to submit an appeal and it is clear that the evidence in question could not have been prepared before the deadline to submit the appeal. (Decision of 07.09.2021, A-008-2020, *Sustainability Support Service (Europe)*, para. 36; Decision of 22.03.2022, Case A-003-2020, *Campine Belgium*, para. 35, 44; Decision of 22.03.2022, Case A-004-2020, *Tribotecc Austria*, para. 35, 44; Decision of 22.02.2022, Case A-005-2020, *S. Goldmann*, para. 35, 44; Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 142)

> ***Illustration***. During the hearing, the appellant claimed that certain of ECHA's oral responses constituted new evidence. The BoA observed however that the argument in issue was raised for the first time by the appellant in its final submission prior to the closure of the written procedure and that ECHA was not given the opportunity prior to the hearing to respond to those arguments. In view of this fact, the BoA considered that ECHA's delay in offering evidence to be justified pursuant to Article 12(1) RoP. (Decision of 03.12.2014, Case A-005-2013, *Vanadium* (I), para. 48)

> ***Illustration***. A review of an older study was announced by the appellants in a presentation to the MSC. The appellants also referred to the on-going review in their notice of appeal. Furthermore, it was not until the appellants received the draft decision that they became aware that the eMSCA interpreted the results of the study as indicating a potential inhalation toxicity concern. It is therefore understandable that they had not initiated a review before that time. The time it took to submit the review was also not unreasonable. Therefore, the delay was duly justified. (Decision of 30.06.2017, Case A-015-2015, *Evonik Degussa*, para. 50-52)

Evidence acquired of BoA's own motion. Requests by the BoA for the submission of evidence should not be read restrictively. (Decision of 19.06.2013, Case A-005-2011, *Honeywell Belgium*, para. 53)

3.6. Evidence not previously available to ECHA

General. When examining whether information or evidence submitted in support of the notice of appeal that was not available to ECHA during the decision-making procedure leading to the adoption of the contested decision is admissible, the BoA needs to ascertain whether such information or evidence supports new facts or is supporting facts already alleged during the decision-making procedure before ECHA. (Decision of 19.06.2013, Case A-001-2012, *Dow Benelux*, para. 46; Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 36; Decision of 25.09.2013, Case A-007-2012, *Italcementi*, para. 51-54; Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 133; Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum*, para. 31; Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 123)

> ***Illustration***. The appellant submitted certain study summaries with the notice of appeal. This evidence was however intended to demonstrate that the substances at issue also cause kidney effects and that the source substances and the substance are therefore likely to have similar toxicological effects. (Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 133)

3.7. Incidental pleas of illegality

General. There is no provision similar to Article 277 TFEU applicable to proceedings before the BoA. Applying Article 277 TFEU by analogy to proceedings before the BoA would extend the list of ECHA decisions set out in Article 91(1) REACH which can be appealed before the BoA. This would be contrary to Article 91(1) REACH. (Decision of 30.06.2017, Case A-015-2015, *Evonik Degussa,* para. 66, 70)

Claims relating to the compatibility of legislative acts (REACH, BPR, Fee Regulations) with the EU Treaties are inadmissible as they transcend the competence of the BoA. (Decision of 07.10.2011, Case A-004-2011, *Kronochem*, para. 66; Decision of 19.06.2013, Case A-001-2012, *Dow Benelux*, para. 58; see also Decision of 25.09.2015, Case A-020-2015, *Lysoform and Others*, para. 34; Decision of 25.09.2015, Case A-019-2015, *Lysoform and Others*, para. 34; Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum*, para. 122-123)

> ***Illustration***. An argument was formally directed against the contested decision but actually challenged the proportionality of the REACH Regulation, for which the BoA is not competent. (Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum*, para. 122-123)

3.8. Pleas in law raised by an intervener

Admissibility. Under Article 8 of the Rules of Procedure4 an intervener may submit a statement in intervention which contains, amongst other information, the pleas in law and the arguments of fact relied on. An intervener may raise new pleas insofar as they are not entirely unconnected to the pleas raised by the main party and do not modify the subject matter of the case. (Decision of 21.06.2023, Case A-004-2022, *Symrise*, para. 35-36)

4. INTERVENTION

4.1. General

The case law of the ECJ on Art. 40 of its Statute provides guidance for the interpretation of Art. 8(1) RoP. (Intervention Decision of 26.09.2012, A-004-2012, *Lanxess Deutschland (ECEAE)*, para. 17; Intervention Decision of 08.11.2011, Case A-005-2011, *Honeywell Belgium (ECEAE)*, para. 16; Intervention Decision of 26.04.2012, Case A-001-2012, *Dow Benelux (ECEAE)*, para. 16; Intervention Decision of 05.09.2012, Case A-003-2012, *Thor*, para. 16)

Article 8(1) RoP should be interpreted with due regard to the REACH Regulation and the administrative nature of appeal proceedings. The REACH Regulation foresees the involvement of stakeholders in ECHA's work through consultations and in the workings of the committees that are established within ECHA. This involvement aims to help ensure that various interests are taken into account in ECHA's decision-making. (Intervention Decision of 12.02.2016, A-014-2015, para. 18)

Issues relating to the substance of a case cannot be decided in the context of examining an application for leave to intervene. (Decision of 03.05.2017 (ECEAE), Case A-013-2016, *BASF Personal Care and Nutrition*, para. 36; Decision of 03.05.2017 (PISC), Case A-013-2016, *BASF Personal Care and Nutrition*, para. 38)

For an example concerning an intervention submitted one day too late, see Decision on application to intervene of 29.09.2015, Case A-08-2014, *BASF Grenzach (ECEAE)*, para. 7-8.

An applicant supporting ECHA faces an inherent difficulty in complying with Article 8(4)I RoP as it will not necessarily know what arguments ECHA will make as it has not seen the defence. Covering the possible claims ECHA might raise cannot be considered to be an infringement of Article 8(3) RoP at the stage of lodging an application to intervene. (Intervention Decision of 15.03.2016, Case A-022-2015, *Michelin (German CA)*, para. 11)

An intervener iI, in general, not entitled to raise an objection of inadmissibility not raised by any of the parties. (Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 47)

An intervener supporting ECHA is not entitled to seek to have an appeal dismissed as unfounded, and to make substantive arguments in support of its intervention, when ECHA has only raised an objection of inadmissibility. (Decision of 30.05.2017, Case A-022-2015, *Michelin*, para. 62)

***Pleas and arguments entirely unconnected to the appeal*.** An intervener may set out arguments as well as pleas independently, in so far as they support the form of order sought by one of the main parties and are not entirely unconnected with the issues underlying the dispute, as established by the applicant and defendant, as that would otherwise change the subject-matter of the dispute. In the present application, the applicant's argument was clearly unconnected from the issues raised by the appellant and would therefore have been rejected also for this reason. (Intervention Decision of 15.12.2017, Case A-006-2017, *Climax Molybdenum (Plansee)*, para. 23; Intervention Decision of 15.12.2017, Case A-006-2017, *Climax Molybdenum (Sadaci)*, para. 23; see also Decision of 24.03.2020, Case A-006-2018, *Emerald Kalama Chemical and Others*, para. 43)

The applicant to intervene need only show its interest in the possible outcome of the appeal and does not have to address the substantive claims raised in the appeal. (Intervention Decision of 15.03.2016, Case A-022-2015, *Michelin (German CA)*, para. 21)

If the application to intervene is granted, the BoA cannot limit its scope to one particular issue. (Intervention Decision of 12.02.2016, Case A-014-2015, *Grace (ClientEarth and CIEL)*, para. 39)

4.2. Interest in the result of a case

4.2.1. General

An interest in the outcome of the case must be understood as being a direct and existing interest in the form of order sought by the party the applicant wishes to support. To that end, it is necessary to determine that the applicant is directly affected by the contested decision and that its interest in the result of the case is established. (Intervention Decision of 08.11.2011, Case A-005-2011, *Honeywell Belgium (Du Pont)*, para. 13; Intervention Decision of 06.04.2016, Case A-001-2016, *Troy Chemical (Thor)*, para. 10)

The expression 'result' means the operative part of the final decision of the BoA. (Intervention Decision of 15.03.2016, Case A-022-2015, *Michelin (German CA)*, para. 13; Intervention Decision of 06.04.2016, Case A-001-2016, *Troy Chemical (Thor)*, para. 10)

As the outcome of the appeal cannot be prejudged, it is sufficient for an applicant to intervene to establish that there is a real possibility that the appeal could lead to a specific consequence. (Intervention Decision of 15.03.2016, Case A-022-2015, *Michelin (German CA)*, para. 20)

As an application for intervention is appraised on its specific facts, it is for an applicant to establish, in each individual case where intervention is sought, its interest in the result of that specific case. (Intervention Decision of 26.09.2012, Case A-004-2012, *Lanxess Deutschland (ECEAE)*, para. 28)

4.2.2. Member States

Compliance check prior to substance evaluation. A substance evaluation to be performed by the Member State Competent Authority applying for leave to intervene will have to take into account *inter alia* information submitted following a compliance check. Such an authority therefore has a direct and existing interest in the result of an appeal concerning the compliance check decision within the meaning of Article 8(1) RoP. (Intervention Decision of 11.02.2015, Case A-011-2014, *Huntsman P&A UK* (French CA), para. 17-18)

Substance evaluation. The evaluating Member State Competent Authority (eMSCA) has an interest in an appeal challenging the statement of reasons of a substance evaluation decision, because the BoA's decision could have an impact on the available data and the applicant's ability to complete the substance evaluation and to prepare the follow-up actions pursuant to Article 48 REACH. (Intervention Decision of 15.03.2016, Case A-022-2015, *Michelin (German CA)*, para. 16)

The eMSCA has an interest in an appeal challenging a substance evaluation decision, because the BoA's decision could require it to re-evaluate the substance and possibly prepare a new draft decision and could have an impact on the applicant's ability to complete the substance evaluation, which affects its workload planning for future years, on the follow-up actions that it is required to conduct pursuant to Article 48 REACH. (Intervention Decision of 05.12.2014, Case A-009-2014, *Albemarle Europe (UK CA)*, para. 5-8 and 13)

Note: Since June 2016, an eMSCA that wishes to intervene no longer needs to establish an interest in the result of the case (new Article 8(1), second subparagraph, RoP).

4.2.3. Other registrants of the same substance

Compliance check. Co-registrants are directly affected by the outcome of an appeal lodged by the lead registrant for the same substance since they have cooperated in the preparation of the joint submission and are required to refer to the lead registration dossier. Furthermore, the REACH Regulation requires data to be shared and it is likely that the applicant will have to bear a share of the costs incurred for the additional testing required. (Intervention Decision of 08.11.2011, Case A-005-2011, *Honeywell Belgium (Du Pont)*, para. 17-18)

Subsequent co-registrants in substance evaluation. Since the information requested in the contested decision may require amendments to the joint submission, including possible changes to the substance identification, the applicant for leave to intervene was directly affected by the contested decision. (Intervention Decision of 02.12.2015, Case A-015-2015, *Evonik Degussa (Solvay Advanced Silicas Poland)*, para. 14)

4.2.4. Animal welfare organisations

In light of the objectives and general framework of the REACH Regulation, the representation of non-economic interests such as animal welfare is especially desirable during the course of appeal proceedings. (Intervention Decision of 08.11.2011, Case A-005-2011, *Honeywell Belgium (ECEAE)*, para. 22; Intervention Decision of 26.04.2012, Case A-001-2012, *Dow Benelux (ECEAE)*, para. 22-23); Intervention Decision of 26.09.2012, Case A-004-2012, *Lanxess Deutschland (ECEAE)*, para. 19; Intervention Decision of 05.09.2012, Case A-003-2012, *Thor*, para. 20)

An animal rights association may be admitted to intervIne if (i) it represents an appreciable number of operators; (ii) it has as one of its object the protection of the interests of its members whose common object is to minimise animal testing, (iii) the case raises questions of principle liable to affect those members (iv) those interests are affected to an appreciable extent. Moreover, accredited stakeholders may be considered to satisfy more readily the requirements for intervention. (Intervention Decision of 08.11.2011, Case A-005-2011, *Honeywell Belgium (ECEAE)*, para. 24-30; Intervention Decision of 26.04.2012, Case A-001-2012, *Dow Benelux (ECEAE)*, para. 19; Intervention Decision of 05.09.2012, Case A-003-2012, *Thor*, para. 18-19, 22 and 28-29; Intervention Decision of 26.09.2012, Case A-004-2012, *Lanxess Deutschland (ECEAE)*, para. 25-27; Intervention Decision of 05.04.2017, Case A-009-2016, *Symrise (ECEAE)*, para. 14; Intervention Decision of 05.04.2017, Case A-009-2016, *Symrise ECEAE)*, para. 18)

The interests in question may be non-economic as well as economic in nature. (Intervention Decision of 26.09.2012, Case A-004-2012, *Lanxess Deutschland (ECEAE)*, para. 19 and 29; Intervention Decision of 05.04.2017, Case A-009-2016, *Symrise (ECEAE)*, para. 14; Intervention Decision of 05.04.2017, Case A-009-2016, *Symrise (ECEAE)*, para. 18)

When assessing an application to intervene, the BoA must have regard to the role given to stakeholders in the REACH Regulation and in the documents endorsed by ECHA's governing body. (Intervention Decision of 12.02.2016, Case A-014-2015, *Grace (ClientEarth and CIEL)*, para. 20; Intervention Decision of 10.02.2016, Case A-015-2015, *Evonik Degussa (ClientEarth and CIEL)*, para. 24)

The fact that an applicant is an accredited stakeholder that participates regularly in meetings of the Member State Committee (MSC) and the Risk Assessment Committee (RAC) seeking to minimise the amount of animal testing sets the applicants interest apart from any general or collective interest. (Intervention Decision of 08.11.2011, Case A-005-2011, *Honeywell Belgium (ECEAE)*, para. 35)

The extent of the applicant/accredited stakeholder's involvement in decision-making is not decisive for the purposes of assessing whether the applicant fulfils the criteria enabling it to intervene. (Intervention Decision of 26.04.2012, Case A-001-2012, *Dow Benelux (ECEAE)*, para. 33)

When assessing the application to intervene by an NGO in a case related to the substance evaluation of a nanomaterial, the BoA first examined whether the NGO had a general interest in REACH, which it did considering its status as accredited stakeholder, and second concluded that it also had a long-standing interest in the regulation of nanomaterials considering the objective of that NGO, its publications on the topic and involvement in a related public consultation held by the Commission. (Intervention Decision of 12.02.2016, Case A-014-2015, *Grace (ClientEarth and CIEL)*, para. 27-32; Intervention Decision of 10.02.2016, Case A-015-2015, *Evonik Degussa (ClientEarth and CIEL)*, para. 30-39)

Article 8(1) RoP does not require that an applicant's activities would have to be specifically focused on the actual substance concerned. (Intervention Decision of 12.02.2016, Case A-014-2015, *Grace (ClientEarth and CIEL)*, para. 33; Intervention Decision of 10.02.2016, Case A-015-2015, *Evonik Degussa (ClientEarth and CIEL)*, para. 37)

The fact that the contested decision was not addressed to the applicant or that it does not create legal obligations vis-à-vis the applicant are not relevant for the purposes of establishing

an interest within the meaning of Art. 8(1) RoP for a representative association. (Intervention Decision of 08.11.2011, Case A-005-2011, *Honeywell Belgium (ECEAE)*, para. 34)

4.2.5. Trade associations

General. A representative association may be granted leave to intervene in a case if, firstly, it represents an appreciable number of those active in the field concerned, secondly, its objects include that of protecting its members' interests, thirdly, the case may raise questions of principle of affecting those interests, and, fourthly, the interests of its members may therefore be affected to an appreciable extent by the judgment to be given. (Intervention Decision of 13.10.2015, Case A-012-2014, *Huntsman Holland*, para. 13)

> ***Illustration***. A US chemical trade association did not have standing because it was not an Accredited Stakeholder Organisation, although this is not decisive, and it did not represent an appreciable number of those active in the field concerned, i.e., the companies involved in placing the substance concerned in the market in the EU. It did not include registrants of the substance concerned but only companies presumably affiliated with two of these registrants. (Intervention Decision of 13.10.2015, Case A-012-2014, *Huntsman Holland*, para. 20)

4.2.6. Addressees of the contested decision

The appellant requested the BoA to annul the contested decision in so far as it grants the applicant permission to refer to certain studies owned by it. The appeal therefore influenced the outcome of the applicant's application to be included on the list of active biocidal substance and product suppliers published in accordance with Article 95 BPR. Therefore, the non-inclusion of the applicant on the Article 95 list would have the consequence of restricting its access to the market. The applicant, which was also the addressee of the contested decision, was therefore directly affected by the present appeal. (Intervention Decision of 06.04.2016, Case A-001-2016, *Troy Chemical (Thor)*, para. 11)

4.3. Formal requirements for applications for leave to intervene

Application submitted jointly. Where two applicants submitted one and the same application to intervene and it is established that one has an interest in intervening, there was no need to examine the other applicant's interest in intervening. (Intervention Decision of 12.02.2016, Case A-014-2015, *Grace (ClientEarth and CIEL)*, para. 38; Intervention Decision of 10.02.2016, Case A-015-2015, *Evonik Degussa (ClientEarth and CIEL)*, para. 45)

Legal personality. In order to be granted leave to intervene, an applicant must prove inter alia that it had legal personality before the time limit set for applications to intervene, or that it possessed all the characteristics which constitute the foundation of such legal personality. (Intervention Decision of 16.01.2013, Case A-006-2012, *Momentive Specialty Chemicals (PISC)*, para. 23)

5. OTHER ISSUES RELATING TO THE APPEAL PROCEDURE

5.1. Miscellanea

Requalification of pleas by BoA. The BoA found that, rather than contending the absence of legal basis, the arguments raised by the appellant under this plea directly concerned the assessment of the registration dossier performed by ECHA. The BoA therefore examined whether ECHA made an error of assessment. (Decision of 01.08.2016, Case A-014-2014, *BASF Pigment*, para. 26; Decision of 01.08.2016, Case A-003-2015, *BASF Pigment*, para. 45; Decision of 07.10.2016, Case A-017-2014, *BASF*, para. 72-73)

On rectification of obvious mistakes in a BoA decision (Article 26 RoP) see Decision of 19.12.2016, Case A-013-2014, *BASF*.

Article 26 RoP does not provide that applications for rectification may be submitted by an intervener. As a result, it must be held that interveners are not entitled to submit requests for rectification within the meaning of Article 26 RoP. (Joined Cases A-003-2018, A-004-2018 and A-005-2018, Decision of 10.02.2020, *BASF and Others*, para. 8)

Suspensive effect. The appellant sought the annulment of the requirement to extend cohort 1B in the EOGRTS to include the F2 generation, but not the requirement to provide information on an EOGRTS in its entirety. However, the appellant could not be expected to commence the study without certainty as to whether an extension of cohort 1B to include the F2 generation was necessary. In addition, the contested decision states that 'the carcinogenicity study shall be conducted before the EOGRTS and the PNDT study. The results from the carcinogenicity study shall be used to consider if further testing for EOGRTS and PNDT is necessary'. As a result, in the present case, the suspensive effect provided for in Article 91(2) REACH must be considered as applying to the request to provide information on an EOGRTS in its entirety. (Decision of 09.04.2019, Case A-001-2018, *BrüggemannChemical, L. Brüggemann*, para. 88)

5.2. Burden of proof

General. The burden of proof to establish that a contested decision was vitiated by an error rests on the appellant. (Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 119)

Prima facie proof. An appellant cannot be required to prove that no analytical procedure was available at a certain point in time, as the burden of such proof would be excessively difficult or even impossible to discharge. Therefore, if an appellant puts forward credible evidence that there were no appropriate analytical methods available, the burden of proving that an appropriate test method was available shifts onto ECHA. (Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 119)

5.3. Rectification of a contested decision by the Executive Director

General. The Executive Director may rectify any part of a contested decision, be it its operative part or the reasoning of the contested decision. (Decision of 25.09.2013, Case A-007-2012, *Italcementi*, para. 3724nterpretat***matio in peius***. The discretionary powers of the Executive Director of ECHA to rectify contested decisions are limited only by the legal consequences of rectification, namely that the registrant must not be placed in a less favourable position than the one in which he would have been without rectification. (Decision of 25.09.2013, Case A-007-2012, *Italcementi*, para. 39)

Partial rectification. When an appealed decision is rectified and the appeal proceedings are pursued, the BoA considers that the appeal has been filed against the contested decision as rectified. (Decision of 25.09.2013, Case A-007-2012, *Italcementi*, para. 45)

Full withdrawal. As the contested communication, requesting the appellant to join a joint submission, had been rectified by withdrawing it in its entirety, there was no decision to review

and the appeal had therefore become devoid of purpose in its entirety. (Decision of 05.02.2020, Case A-022-2018, *Sustainability Support Service (Europe)*, para. 20)

Rectification after 30-day period. The amending decision was adopted after the 30-day period provided under Article 93(1) REACH. It follows that that Article cannot constitute the legal basis for the amending decision. (Decision of 24.05.2018, Case A-001-2017, *Cardolite Specialty Chemicals*, para. 18; Decision of 24.05.2018, Case A-003-2017, *Cardolite Specialty Chemicals*, para. 18)

Even an administrative act which has created individual rights can be withdrawn under certain conditions. A fortiori, ECHA may withdraw a decision which has not created individual rights but rather obligations, or amend it in a way that is favourable to its addressees, provided that it follows the correct procedure. In this case, the amending decision was adopted under the procedure in Articles 40, 50 and 51 REACH, the same that had been used for the adoption of the contested decision. It follows that the amending decision validly amended the contested decision. (Decision of 24.05.2018, Case A-001-2017, *Cardolite Specialty Chemicals (I)*, para. 19-23; Decision of 24.05.2018, Case A-003-2017, *Cardolite Specialty Chemicals (III)*, para. 19-23)

5.4. Confidentiality of information

5.4.1. General

The BoA cannot rely on any elements which have not been the subject of disclosure between the principal parties to the proceedings. The BoA cannot base its decisions on facts and documents of which the parties have not been able to take cognisance and in relation to which they have not been able to set out their views. Such a course would amount to a breach of a party's right to be heard. (Confidentiality Decision of 05.09.2011, Case A-001-2010, *EPZ*, para. 10-11; Confidentiality Decision of 26.06.2012, Case A-005-2011, *Honeywell Belgium*, para. 8)

The Chairman may nevertheless allow parts of a document or other evidence to remain undisclosed, so long as those parts do not relate to evidence which is material to the issue of fact in question, unless they would tend to deprive the rest of the rest of the document of its probative value. (Confidentiality Decision of 05.09.2011, Case A-001-2010, *EPZ*, para. 12)

There exists a presumption that confidentiality cannot be granted for the information necessary for an announcement ex Art. 6(6) RoP. It is for the party requesting confidentiality to rebut that presumption by reasoned request. (Confidentiality Decision of 27.05.2011, Case A-004-2011, *Kronochem*, para. 13-14)

The Chairman's decision on confidentiality applies to the announcement of an appeal and to any final decision. In the event a third party is granted leave to intervene, the Chairman may need to re-examine the findings in his previous decision. (Confidentiality Decision of 29.07.2011, Case A-005-2011, *Honeywell Belgium*, para. 14 and 17; Confidentiality Decision of 04.07.2012, Case A-003-2012, *Thor*, para. 12)

Documents should not be submitted to the BoA in a redacted version. (Confidentiality Decision of 29.07.2011, Case A-005-2011, *Honeywell Belgium,* para. 21-24)

No document properly submitted to the BoA can be returned or destroyed. (Confidentiality Decision of 29.07.2011, Case A-005-2011, *Honeywell Belgium*, para. 28; however, cf. Confidentiality Decision of 05.09.2011, Case A-001-2010, *EPZ*, para. 15)

The Chairman is not bound by a finding of confidentiality by ECHA or one of the committees working under its auspices. (Confidentiality Decision of 29.07.2011, Case A-005-2011, *Honeywell Belgium*, para. 25)

Requests for confidential treatment are analysed on a case-by-case basis. When a confidentiality decision has been adopted, non-confidential information can be made public in the announcement and in any final decision without seeking an appellant's prior consent. (Confidentiality Decision of 29.07.2011, Case A-005-2011, *Honeywell Belgium*, para. 26-27)

When a confidentiality request is decided upon after ECHA and the appellant have agreed on a settlement in principle and it is apparent that the appeal shall be withdrawn before its announcement, no legitimate interests of interveners would be affected by withholding information. (Confidentiality Decision of 05.02.2014, Joined Cases A-011-2013 to A-015-2013, [Confidential], para 16)

Applicants for confidential treatment should foresee the possibility that some of the information forming part of their appeal may need to be made public. (Confidentiality Decision of 12.06.2013, Case A-003-2013, *Poudres Hermillon*, para. 8)

The right of access to documents held by EU institutions is generally founded on possession, not ownership. (Confidentiality Decision of 26.06.2012, Case A-005-2011, *Honeywell Belgium*, para. 20-22)

5.4.2. Legitimate private interests and public interest

Decisions on confidentiality require an assessment of the legitimacy of the private interest opposing disclosure of information and weighing this against the public interest in activities of the EU institutions taking place as openly as possible. Moreover, the special interest of any potential intervener must be taken into account, which amounts to a general right to participate in proceedings that affect the intervener's legal interests. (Confidentiality Decision of 11.04.2011, Case A-003-2011, *BASF*, para. 9 and 14)

The requirement of legitimacy is satisfied where the existence of a commercial interest would be undermined as a result of disclosure. (Confidentiality Decision of 11.04.2011, Case A-003-2011, *BASF*, para. 13)

In assessing whether there is a legitimate commercial interest, regard shall be had to an appellant's SME status which makes it more economically vulnerable. (Confidentiality Decision of 05.02.2014, Joined Cases A-011-2013 to A-015-2013, [Confidential], para. 11)

The harm claimed by the appellant in consequence of disclosure must be reasonably foreseeable, not hypothetical. (Confidentiality Decision of 29.07.2011, Case A-005-2011, *Honeywell Belgium*, para. 47)

Where the appellant has not substantiated a request for confidential treatment, the Chairman is unable to assess whether the private interests of the appellant outweigh the public's right to be informed. In these circumstances, the request can only be accepted in so far as the information and documents which it covers can be considered confidential by their very nature (e.g. financial and legal identity, proof of payment of registration fee). Furthermore, the documents were not required for either the announcement or the final decision. (Confidentiality Decision of 27.05.2011, Case A-004-2011, *Kronochem*, para. 20-23; Confidentiality Decision of 29.07.2011, Case A-005-2011, *Honeywell Belgium*, para. 102)

5.4.3. Requests submitted by ECHA

Since the RoP are silent on who should decide on a confidentiality request when it is submitted by ECHA, the procedure in Art. 6(2) subpara. 2 RoP applies by analogy. (Confidentiality Decision of 05.09.2011, Case A-001-2010, *EPZ*, para. 8; Confidentiality Decision of 27.10.2011, Case A-005-2011, *Honeywell Belgium*, para. 9; Confidentiality Decision of 26.06.2012, Case A-005-2011, *Honeywell Belgium*, para. 6)

5.4.4. Examples

Identity of the appellant. The name of the registrant constitutes a minimum piece of information which it is necessary to disclose in order protect the rights and legitimate interest of interveners. (Confidentiality Decision of 15.10.2009, Case A-001-2009, *Specialty Chemicals*, para. 23-27)

If, however, before announcing the appeal the appellant and ECHA have agreed in principle on the terms of the settlement and subsequently the appellant will withdraw the appeal, there will be no possibility for potential intervener to participate in the case. In such a case, the legitimate

interests of interveners and the public interest to give transparent information on the BoA would not be jeopardised by not disclosing the name of the appellant, particularly when the appellant is an SME and the case relates in principle to a mere administrative issue within the registration process. (Confidentiality Decision of 05.02.2014, Joined Cases A-011-2013 to A-015-2013, [Confidential], para. 13 ff.)

Identity of the substance. Disclosing both the identity of the substance and of the appellant reveals a combination of information which may allow competitors to determine the trade name of the substance in question. It is possible to regard the substance identification as confidential if its disclosure could result in potential commercial harm to the appellant. Such commercial harm can consist in competitors' attempts to take over the appellant's market share by referring to the rejected registration vis-à-vis customers. (Confidentiality Decision of 15.10.2009, Case A-001-2009, *Specialty Chemicals*, para. 17-21; Confidentiality Decision of 11.04.2011, Case A-003-2011, *BASF*, para. 19-23)

When deciding on the existence of overriding reasons of public interest in disclosure, it shall be taken into account that the issue under appeal is of a procedural nature. (Confidentiality Decision of 15.10.2009, Case A-001-2009, *Specialty Chemicals*, para. 21; Confidentiality Decision of 04.07.2012, Case A-003-2012, *Thor*, para. 18)

Information available in the public domain is not confidential. (Confidentiality Decision of 29.07.2011, Case A-005-2011, *Honeywell Belgium*, para. 37-45)

Natural persons. The communication of names of private persons constitutes processing of personal data within the meaning of Regulation (EC) 45/2001. The disclosure of the particulars of natural persons could undermine the protection of the privacy and integrity of individuals. (Confidentiality Decision of 11.04.2011, Case A-003-2011, *BASF*, para. 25-29; Confidentiality Decision of 27.10.2011, Case A-005-2011, *Honeywell Belgium*, para. 19-20; Confidentiality Decision of 29.07.2011, Case A-005-2011, *Honeywell Belgium*, para. 99)

Confidentiality cannot be accepted for those individuals who are nominated as witnesses in the notice of appeal. Their right to object to the processing of personal data must be reconciled with an intervener's right to comment effectively on the evidence brought forward. The fact that interveners have a right to comment on a witness's competence in relation to the appeal (though not to object to that witness) places prospective interveners in a special situation which distinguishes them from the general public. (Confidentiality Decision of 11.04.2011, Case A-003-2011, *BASF*, para. 31)

In deciding on confidentiality, it may be necessary to distinguish between experts who may be called upon to give evidence as witnesses or experts before the BoA, and members of ECHA's staff who are mentioned in procedural documents only incidentally and in their administrative capacity. (Confidentiality Decision of 27.10.2011, Case A-005-2011, *Honeywell Belgium*, para. 19)

Non-disclosure agreements with third parties. While non-disclosure agreements cannot bind any party to the proceedings which is not subject to the agreement, including ECHA, it demonstrates that the other party to the data-sharing agreement could have a justified right to remain anonymous due to its marketing plans and/or sales strategy. Therefore, interests worthy of protection in relation to both parties exist. However, clauses containing general and standard terms which do not manifestly touch on the parties' commercial interest cannot benefit from protection against disclosure. (Confidentiality Decision of 11.04.2011, Case A-003-2011, *BASF*, para. 15-16)

Excerpts from a registration dossier. The request for confidentiality of excerpts from the appellant's registration dossier provided in the BoA decision was rejected. First, the fact that the information in question was not publicly available in that form does not in itself mean that the information should not be published. Second, the eventuality that other registrants might rely on the information in question illegitimately was entirely hypothetical. Moreover, according to the second subparagraph of Article 10(a) REACH, except in cases covered under Articles25(3), 27(6) or 30(3) REACH, a registrant must be in legitimate possession of or have permission to refer to the studies on which it relies for the purpose of registration.

(Decision of the Chairman of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 5-6)

5.5. Experts and witnesses (Article 16 RoP)

The authors of the opinions submitted by the appellant were not admitted as experts and/or witnesses by the BoA. Therefore, those opinions cannot be attributed probative value as opinions of experts or statements of witnesses. They must be considered as documents setting out arguments of the appellant. (Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum*, para. 34-36)

5.6. Change of language (Article 14(3) RoP)

Any request to change the language of the proceedings must be accompanied by a detailed and specific statement of reasons. In this case, the appellant did not try to demonstrate that its rights would be adversely affected if the language was of the proceeding was not changed from English to German, while the appellant seems to be proficient in English, as all its submissions so far were in English. (Decision on request to change the language of the case of 08.02.2013, Case A-003-2012, *Thor*, para. 7)

5.7. Stay of proceedings

After requesting observations from the parties, who did not object, the BoA ordered a stay of proceedings on its own motion due to operational and organisational constraints which may have an impact on the proper administration of pending cases. (Decision on request to stay proceedings of 17.06.2015, Case A-003-2015, *BASF Pigment*, para. 3-4)

The BoA observed that the request for a stay of proceedings was made by the appellants with the purpose of enabling potential settlement discussions between the appellants and ECHA. The BoA noted however that ECHA defends the rectified contested decision, opposes potential settlement discussions with the appellants, and objects to the possible stay of the present proceedings. In view of the above, and in particular as there were no discussions foreseen on a further settlement of the appeal case between the appellants and ECHA, there was no reason to stay the proceedings. (Decision on request to stay proceedings of 09.02.216, Case A-018-2015, *TPP Registrants*, para. 8-9)

5.8. Applications as to costs, refund of the appeal fee

There is no legal basis for the award of legal and other costs by the BoA. (Decision of 21.05.2014, Case A-002-2013, *Distillerie De la Tour*, para. 62-63; Decision of 06.08.2018, *SI Group UK and Others*, Case A-006-2016, para. 201-202)

The appeal fee shall be refunded where, although a contested decision has not been rectified in its entirety, a substantial element of it has been changed or corrected. The appeal fee is to be refunded even if the rectification takes place after the 30-day time limit foreseen in Art. 93(1) REACH. (Decision of 07.10.2011, Case A-004-2011, *Kronochem*, para. 78 and 82)

The eMSCA concluded that '*as* [the Substance] *no longer has any active registrations according to* [ECHA's] *register/dissemination website, the evaluation is terminated with several open concerns*'. This conclusion, which led to the withdrawal of the appeal, renders the initial request for further information inoperative. The Chairman therefore concludes that the contested decision was neither rectified by the Executive Director of ECHA nor was the appeal decided in favour of the appellant. In the present case the conditions for the refund of the appeal fee pursuant to Article 10(4) RoP are not met. (Decision of 12.06.2017, Case A-003-2016, *Solutia Europe*, para. 18-20)

6. GENERAL PRINCIPLES OF EU LAW

6.1. Principle of proportionality

General. The principle of proportionality is a general principle of EU law that applies also to ECHA. Pursuant to that principle, measures adopted by ECHA must not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by the measure in question; when there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued. (Decision of 19.06.2013, Case A-005-2011, *Honeywell Belgium*, para. 115; Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 89; Decision of 23.09.2015, Case A-005-2014, *Akzo Nobel and Others*, para. 52; Decision of 27.10.2015, Case A-006-2014, *International Flavors & Fragrances*, para. 72; Decision of 12.01.2021, Case A-007-2019, Chemours Netherlands, para. 109; Decision of 29.04.2021, Case A-014-2019, *LG Chem Europe*, para. 107; Decision of 09.02.2021, Case A-015-2019, *Polynt*, para. 94; Decision of 10.05.2021, Case A-002-2021, *Lanxess Deutschland and Schirm,* para. 88; Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 74)

Interprétation conforme. REACH must be interpreted , as far as possible, so as to comply with the principle of proportionality. (Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum*, para. 125)

Limited (bound) discretion. In a context in which ECHA has no option but to require the information in direct consequence of the relevant legislation, it does not exercise administrative discretion. It is not therefore required to examine the proportionality of such measures. (Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 118; Decision of 09.04.2014, Case A-001-2013, *Infineum UK*, para. 94; Decision of 07.10.2016, Case A-017-2014, *BASF*, para. 83)

In case of a data-gap ECHA is neither required nor empowered to consider whether it is proportionate, or consistent with Article 25 REACH, for the appellant to be required to submit the information required by the REACH Regulation. (Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum,* para. 118-121; Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 49-51, 96, 132; Decision of 23.08.2022, Case A-004-2021, *Celanese Production Germany*, para. 160; Decision of 31.10.2022, Case A-011-2021, *Croda EU,* para. 87)

Proportionality of potential sanctions. If ECHA concludes in an Article 42(1) REACH follow-up decision that a registration dossier remains non-compliant, it must inform the national authorities of the Member States. It is then the exclusive role of the national authorities of the Member States to impose sanctions that are effective, proportionate and dissuasive, having regard to the facts of the case. ECHA is neither required nor empowered to assess the need or the proportionality of such potential sanctions. (Decision of 09.11.2021, Case A-009-2020, *Polynt* [currently subject to appeal before the General Court], para. 84, 86)

6.2. Principle of legality

Valid legal basis. Although it is necessary to apply the substantive rules in force at the date of the facts in issue, even if those rules are no longer in force when an EU institution adopts an act, the provision which forms the legal basis of an act and empowers the EU institution to adopt the act in question must be in force when the act is adopted. (Decision of 21.09.2020, Case A-023-2018, *Oxiteno Europe*, para. 34 ff.)

Misuse of powers. The concept of misuse of powers refers to cases where an administrative authority has used its powers for a purpose other than that for which they were intended. A decision amounts to a misuse of powers only if it appears, on the basis of objective, relevant and consistent factors, to have been taken to achieve an end other than that stated. (Decision of 27.10.2015, Case A-006-2014, *International Flavors & Fragrances*, para. 54)

When an appellant claims that ECHA misused its powers, the BoA must examine whether ECHA adopted a measure with the exclusive or main purpose of achieving an end other than that stated or evading a procedure specifically prescribed by the REACH Regulation for dealing with the circumstances of the case. The acts of the EU institutions and agencies are in principle presumed to be lawful until such time as they are annulled or withdrawn. It was therefore for the appellant to adduce objective evidence that ECHA acted unlawfully by misusing its power. (Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 43; Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 59)

> ***Illustration***. The BoA rejected the appellant's claim that ECHA used the substance evaluation procedure to avoid addressing the appellant's adaptation under compliance check. (Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 160-161)
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> ***Illustration***. A lack of clarity in regard of the objectives pursued by a contested decision requiring a study was an element indicative of a misuse of administrative discretion. (Decision of 19.06.2013, Case A-005-2011, *Honeywell Belgium*, para. 133, 171 and 180)
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> ***Illustration***. The existence of a national priority plan concerning a substance being evaluated does not show a misuse of powers by the eMSCA and ECHA. (Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 59-63)

When an appellant claims that ECHA acted outside its discretionary powers, the BoA must examine whether, in adopting the act, ECHA exercised its discretion correctly, which presupposes the taking into consideration of all the relevant factors and circumstances of the situation the act was intended to regulate. (Decision of 19.06.2013, Case A-005-2011, *Honeywell Belgium*, para. 77; Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 43)

6.3. Principle of equal treatment

The principle of equal treatment is a general principle of EU law, enshrined in Articles 20 and 21 of the Charter of Fundamental Rights of the EU. The principle of equal treatment requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified. Breach of the principle of equal treatment as a result of different treatment presumes that the situations concerned are comparable, having regard to all the elements which characterise them. The elements which characterise different situations, and hence their comparability, must in particular be determined and assessed in the light of the subject-matter and purpose of the act which makes the distinction in question. The principles and objectives of the field to which the act relates must also be taken into account. (Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 138; Decision of 28.06.2016, Case A-015-2014, *BASF*, para. 66-67)

6.4. Precautionary principle

General. Article 1(3) REACH states that the provisions of the REACH Regulation are underpinned by the precautionary principle. The precautionary principle is a general principle of EU law requiring authorities, in the particular context of the exercise of the powers conferred on them by the relevant rules, to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests. Where there is scientific uncertainty as to the existence or extent of risks to human health or to the environment, the precautionary principle allows the institutions to take protective measures without having to wait until the reality and seriousness of those risks become fully apparent or until the adverse effects materialise. (Decision of 06.08.2018, *SI Group UK and Others*, Case A-006-2016, para. 80-81; Decision of 17 January 2023, *SCAS Europe*, A-009-2021, para. 78)

Interprétation conforme. The precautionary principle may support the interpretation of the legal text. The fact that the contested decision states that it is 'in line' with the precautionary

principle does not mean that it used that principle unlawfully to extend the scope of the relevant legal provisions. (Decision of 28.06.2016, Case A-015-2014, *BASF*, para. 79-80)

6.5. Principle of legal certainty

General. The principle of legal certainty requires that rules of law be clear and precise and predictable in their effect, so that interested parties can ascertain their position in situations and legal relationships governed by EU law. (Decision of 28.06.2016, Case A-015-2014, *BASF*, para. 86; Decision of 09.04.2019, Case A-001-2018, *BrüggemannChemical, L. Brüggemann*, para. 44; Decision of 31.10.2022, Case A-011-2021, *Croda EU,* para. 63; Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 44; Decision of 29.08.2023, *Symrise and Others*, para. 82)

The principle of legal certainty requires that rules of law must be clear and precise, and that their application must be foreseeable by those subject to them. (Decision of 23.08.2022, Case A-004-2021, *Celanese Production Germany*, para. 137)

> ***Illustration***. The cut-off point for dossier update under compliance check was expressed inconsistently and confusingly in the news alert, Practical Guide 12, in the letter accompanying the draft decision, and during the appeal proceedings. ECHA also acted contrary to its own communications regarding the cut-off point. (Decision of 09.04.2019, Case A-001-2018, *BrüggemannChemical, L. Brüggemann*, para. 64)
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> ***Illustration***. In the context of dossier updates during the final stage of decision procedures on compliance, every measure adopted by ECHA which regards the obligations applicable to registrants must be clear and precise and be clearly brought to the notice of those concerned. Persons concerned must be (i) specifically and individually informed in due time and (ii) information made available to registrants regarding rules applicable to them must be clear and precise. Shortcomings may cause a diligent and prudent registrant, exercising a reasonable level of due care, to be mistaken. (Decision of 01.08.2013, Case A-003-2012, *Thor*, para. 80-83, 89, 94, 98)
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> ***Illustration***. The annulment of a completeness check decision in effect amounts to the revocation of the registration number assigned to a registration pursuant to Article 20(3) REACH. In accordance with the case law of the ECJ an advantageous decision may be revoked, even retroactively, where it rests on wrong or incomplete information from the persons concerned, provided doing so does not infringe the principles of legal certainty or legitimate expectations. In case of annulment of the contested completeness check decision, ECHA was required to undertake a fresh completeness check of the submitted registration and, in accordance with the third subparagraph of Article 20(2) REACH, to inform the registrant of the elements which are missing in order for its dossier to be complete, and set a reasonable deadline for the provision of the relevant information. (Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 126, 127)

Notification and legal certainty. Acts producing legal effects must be brought to the notice of those concerned in such a way that they can ascertain exactly the time at which the act comes into being and begins to have legal effects. (Decision of 09.04.2019, Case A-001-2018, *BrüggemannChemical, L. Brüggemann*, para. 44)

Terminology and legal certainty. The explanations of the terms 'grade' and 'form' given in the contested decisions left it unclear whether ECHA meant that separate, or range, information should be provided whenever one of these 'variables' change or exactly what information is needed for each variable. This lack of clarity made it impossible for the appellants to know with any certainty what information they had to provide to comply with the contested decisions. (Decision of 12.10.2016, Case A-008-2015, *Evonik Degussa*, para. 50; Decision of 12.10.2016, Case A-009-2015, *Iqesil*, para. 47; Decision of 12.10.2016, Case A-010-2015, *Rhodia*, para. 48; Decision of 12.10.2016, Case A-011-2015, *J.M. Huber Finland*, para. 50)

Instructions and legal certainty. As part of the principle of legal certainty, registrants must be able to rely on the most recent instruction – e.g. a practical guide – issued by ECHA being

up-to-date and correct. (Decision of 09.04.2019, Case A-001-2018, *BrüggemannChemical L. Brüggemann,* para. 50; Decision of 29.08.2023, *Symrise and Others*, para. 82)

Consequences of a compliance check decision. A compliance check decision finding a data-gap in a registration dossier is a foreseeable consequence of a registrant proposing a read-across adaptation that does not comply with Section 1.5. of Annex XI REACH. Whilst ECHA has to provide adequate grounds for such decisions, the registrant is responsible for complying with the information requirements of the testing Annexes, either by conducting the respective studies or submitting compliant adaptations. It is not the task of ECHA to develop or improve the adaptation on a registrant's behalf. (Decision of 24.03.2020, Case A-006-2018, *Emerald Kalama Chemical and Others*, para. 131)

Follow-up decisions. A follow-up decision under Article 42(1) is strictly limited to assessing whether the data-gaps identified in the initial compliance check decision have been filled. Article 42(1) does not oblige the Agency to set a new deadline. This is consistent with the principle of legal certainty. The possibility that an adaptation may be rejected, and that enforcement measures might ensue following a decision under Article 42(1), is foreseeable to a registrant when it decides whether to submit an adaptation or carry out a study in consequence of a compliance check decision. (Decision of 23.08.2022, Case A-004-2021, *Celanese Production Germany*, para. 149-150)

6.6. Principle of the protection of legitimate expectations

General. Relying on the principle of legitimate expectations is open to any individual which an institution, by giving him precise assurances, has led to entertain legitimate expectations. Regardless of the form in which it is communicated, precise, unconditional and consistent information which comes from an authorised and reliable source constitutes such assurance. (Decision of 01.08.2016, Case A-014-2014, *BASF Pigment*, para. 40; Decision of 01.08.2016, Case A-003-2015, *BASF Pigment*, para. 47; Decision of 23.08.2022, Case A-004-2021, *Celanese Production Germany*, para. 138; Decision of 31.10.2022, Case A-011-2021, *Croda EU,* para. 73; Decision of 29.08.2023, *Symrise and Others*, para. 83)

The principle of the protection of legitimate expectations presupposes that the administration gave the person concerned precise assurances, leading that person to entertain justified expectations. Information which is precise, unconditional and consistent, in whatever form it is given, constitutes such assurances. (Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 45; Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 207)

> ***MSC attendance***. ECHA's communication on MSC attendance did not give a precise, unconditional assurance that it would be allowed to speak in the MSC meeting. (Decision of 08.08.2018, Case A-009-2016, *Symrise*, para. 51)
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> ***Guidance***. Where ECHA has published guidelines on its administrative procedure, its discretion can be limited by such guidelines. (Decision of 10.10.2011, Case A-001-2010, *EPZ*, para. 60; Decision of 09.04.2014, Case A-001-2013, *Infineum UK*, para. 65; Decision of 17.12.2014, Case A-017-2013, *Vanadium* (II), para. 82)
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> ECHA's guidance document indicates the information that is needed to justify a read-across adaptation but does not, and cannot, prejudge ECHA's assessment of whether the information provided fulfils those information requirements. Consequently, the guidance cannot constitute a precise and unconditional assurance that that appellant's read-across adaptation would be accepted in practice and is therefore not capable of giving rise to legitimate expectations in the present case. (Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 156)
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> ***Teleconference***. Discussions during the course of a teleconference do not, in principle, give rise to legitimate expectations on the part of a registrant if it is clearly stated that neither party is bound by the contents of the discussion. (Decision of 09.04.2014, Case A-001-2013, *Infineum UK*, para. 83)

Webinar. Advice given by ECHA in a webinar does not constitute a binding interpretation of the REACH Regulation. In certain situations however communications of ECHA may be considered to give rise to legitimate expectations to third parties. (Decision of 01.08.2016, Case A-014-2014, *BASF Pigment*, para. 40; Decision of 01.08.2016, Case A-003-2015, *BASF Pigment*, para. 47)

6.7. Principle of good administration

General. The right to good administration entails, in particular, a duty for the administration to examine carefully and impartially all the relevant aspects of an individual case and the right of the person concerned to be heard and to receive an adequately reasoned decision. (Decision of 24.11.2020, Case A-004-2019, *ARKEMA*, para. 45; Decision of 29.04.2021, Case A-014-2019, *LG Chem Europe*, para. 108; Decision of 09.11.2021, Case A-009-2020, *Polynt* [currently subject to appeal before the General Court], para. 88)

The right to good administration, which is codified in Article 41 of the Charter of Fundamental Rights of the EU, requires ECHA to examine carefully and impartially all the relevant aspects of the individual case, to gather all the factual and legal material necessary for the exercise of its discretion, and to ensure the proper conduct and the efficiency of the procedures it was implementing. (Decision of 07.09.2021, A-008-2020, *Sustainability Support Services (Europe)*, para. 47; Decision of 09.11.2021, Joined Cases A-006-2020 and A-007-2020, *BASF Colors & Effects and BASF*, para. 68; Decision of 09.11.2021, Case A-009-2020, *Polynt* [currently subject to appeal before the General Court], para. 87; Decision of 10.05.2021, Case A-002-2021, *Lanxess Deutschland and Schirm*, para. 53)

> ***Illustration.*** ECHA cannot presume that a registrant which downgrades its tonnage band after receiving a draft compliance check decision uses that tonnage downgrade as a means to escape its responsibilities. A systematic and absolute refusal to take into account any tonnage downgrade after the receipt by the registrant concerned of a draft compliance check decision constituted a breach by ECHA of its duty to assess each case individually. (Decision of 09.11.2021, Joined Cases A-006-2020 and A-007-2020, *BASF Colors & Effects and BASF*, para. 70-71)

A lack of clarity, accuracy and precision in communications by ECHA, such as to induce a diligent and reasonably prudent registrant exercising due care to mistake his obligations, can constitute a breach of the principle of good administration. (Decision of 10.10.2011, Case A-001-2010, *EPZ*, para. 110, 151 and 168)

Rectification by the Executive Director. ECHA should take into consideration all the consequences that act may entail. Consequently, ECHA's administrative action should pursue properly and efficiently the interests of ECHA while also appropriately recognising the rights and interests of persons affected by its decision. (Decision of 25.09.2013, Case A-007-2012, *Italcementi*, para. 62)

Scientific excellence, transparency and independence. ECHA's assessment of all relevant aspects of the individual case is carried out as thoroughly as possible on the basis of the principles of scientific excellence, transparency and independence. (Decision of 18.08.2020, Case A-010-2018, *Symrise*, para. 202; Decision of 23.02.2021, Joined Cases A-016-2019 to A-029-2019, *Lubrizol France and Others*, para. 123; Decision of 07.09.2021, A-008-2020, *Sustainability Support Service (Europe)*, para. 47)

Linguistic regime. Notifications sent and decisions adopted during compliance check procedures do not constitute a reply to an earlier document, namely the registration dossier, within the meaning of Article 2 of Council Regulation No 1/1958. Such communications must, in principle, be sent to a registrant in the official language of his Member State of establishment pursuant to Art. 3, Council Reg. 1/1958, unless there has been an explicit agreement to the contrary based on a genuine choice. A reply to a communication sent in a language other than that of the Member State of establishment does not fulfil these requirements. (Decision of 21.05.2014, Case A-002-2013, *Distillerie De la Tour*, para. 42-47)

Reference numbering. It is poor administrative practice to attribute the same reference number to two separate letters with the same date, on the same issue, with different content, to two parties. (Decision of 03.12.2014, Case A-005-2013, *Vanadium REACH Forschungs- und Entwicklungsverein* (I), para. 56)

Diligent and prudent registrant. Every registrant has the duty to act in a diligent and prudent manner in fulfilling its obligations pursuant to the REACH Regulation. While the principle of respect for the rights of defence imposes on the EU administration a number of procedural obligations, it also implies a certain amount of diligence on the part of the party concerned. Accordingly, if the party concerned considers that its rights of defence have not been respected, or have not been adequately respected, in the administrative procedure, it is for the party to take the measures necessary to ensure that they are respected or, at the very least, to inform the competent administrative authority of that situation in good time. (Decision of 13.11.2014, Case A-020-2013, *Ullrich Biodiesel*, para. 28; Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 129; Decision of 01.08.2016, Case A-014-2014, *BASF Pigment*, para. 76; Decision of 01.08.2016, Case A-003-2015, *BASF Pigment*, para. 77)

6.8. Tempus regit actum

At the time the Contested Decision was adopted, Column 1 of Section 9.3. of Annex VIII did not include the bioaccumulation study requested in the Contested Decision as a standard information requirement. Furthermore, Column 2 of Section 9.3. of Annex VIII did not contain a triggering provision for additional information on bioaccumulation equivalent to Column 2 of Section 9.2. of Annex VIII in relation to degradation. Such a triggering provision has been added to Column 2 of Section 9.3. of Annex VIII to the REACH Regulation by Regulation (EU) 2022/477. However, that amendment to the REACH Regulation became applicable after the adoption of the Contested Decision and, therefore, is not relevant to the present case. (Decision of 14.02.2023, Case A-012-2021, *Covestro*, para. 113-115)

> ***Illustration***. (Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 195)

7. PROCEDURAL RIGHTS, REQUIREMENTS AND SAFEGUARDS

7.1. Right to be heard

7.1.1. General

Definition. Observance of the right to be heard is, in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of community law which must be guaranteed even in the absence of any rules governing the proceedings in question. That principle requires that the addressee of a decision which significantly affects its interests should be given the opportunity to effectively make known its views on the correctness and relevance of the facts, objections and circumstances put forward by the institution (Decision of 29.07.2015, Case A-019-2013, *Solutia Europe*, para. 88) as well as the information requirements that the decision will impose (Decision of 08.08.2018, Case A-009-2016, *Symrise*, para. 66; Decision of 19.12.2016, Case A-018-2014, *BASF,* para. 470)

Observance of the right to be heard presupposes not only that the concerned person has the opportunity to put forward its arguments, but also that the administration takes those arguments into account, carefully and impartially, in coming to its decision. (Decision of 17.11.2020, Case A-006-2019, *Sharda Europe*, para. 50-52)

The context of scientific uncertainty under substance evaluation regarding the potential concern or concerns to be clarified and the different tests available to do so, coupled with the broad margin of discretion available to ECHA under the substance evaluation process, makes it all the more important that the right to be heard should be respected. (Decision of 08.08.2018, Case A-009-2016, *Symrise*, para. 82)

Purpose. The right to be heard is not a mere procedural formality. It is a fundamental right and serves a twofold purpose. First, the right to be heard allows the addressees that significantly affect their interests to defend themselves by influencing the decision-making process. Second, the right to be heard ensures that decisions are taken with all due care and prudence, so that all relevant factors and circumstances are taken into account and the decision is substantively correct. (Decision of 08.08.2018, Case A-009-2016, *Symrise*, para. 67-69)

Right to be heard as an individual right. The right to be heard is an individual right and only those who are affected by a potential breach thereof can bring an action alleging its violation. (Decision of 07.12.2016, Case A-013-2014, *BASF*, para. 58)

Consequence of a breach. A breach of the right to be heard results in the annulment of the decision only if, had it not been for such an infringement, the outcome of the procedure might have been different. (Decision of 29.01.2019, Case A-005-2017, *Thor*, para. 61; Decision of 24.11.2020, Case A-004-2019, ARKEMA, para. 74; Decision of 17.12.2014, Case A-017-2013, *Vanadium* (II), para. 104; Decision of 07.12.2016, Case A-013-2014, *BASF*, para. 83-86)

> ***Illustration:*** The appellant argued that its right to be heard was infringed by the fact that, during the appeal proceedings, the Agency changed the reasoning justifying the request for information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX. The BoA rejected the argument as the appellant had not demonstrated that the outcome of the compliance check procedure might have been different had the interpretation of Column 2 of Section 9.2. of Annex IX presented by the Agency during the appeal proceedings been relied on in the contested decision. (Decision of 27.09.2022, Case A-005-2021, *Albemarle Europe,* para. 69-72)

7.1.2. Scope

General. The right to be heard extends to all factual and legal material upon which a decision is based, but not to the final position which the Authority intends to adopt. (Decision of 19.06.2013, Case A-001-2012, *Dow Benelux*, para. 78)

Expected assessment of all legal criteria for a column 2 adaptation. The right to be heard guarantees that the parties will not be confronted with a completely unexpected decision. The appellant should clearly have anticipated that the degree of human exposure, the third condition of the respective Column 2 adaptation, would be assessed by ECHA in the contested decision. (Decision of 01.08.2016, Case A-014-2014, *BASF Pigment*, para. 72)

Assessment of information provided by the registrant. A party which itself submitted the facts in question was by definition in a position to state their possible relevance to the resolution of the case at the time when it submitted them. (Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 72)

No request for additional information. The Appellant argues that the Agency breached its right to be heard as the Contested Decision was adopted without first requesting the Appellant to substantiate its claim with additional information. It is the sole responsibility of the registrants to generate, gather and submit to the Agency the information that they consider will fulfil the information requirements of the REACH Regulation. In the present case, the Agency correctly limited its examination to the information submitted by the Appellant in its registration and during the decision-making procedure leading to the Contested Decision. (Decision of 21.06.2023, Case A-004-2022, *Symrise*, para. 117-119)

Information provided in a dossier update. The BoA observes that the information relating to the read-across in the updated dossier should already have been included in the registration dossier when it was first submitted. In that case, ECHA would have had the possibility to assess this information and include its conclusions on it in the draft decision, on which the appellant would then have been able to comment in accordance with Articles 50 and 51 REACH. However, the appellant did not submit this information at the time of its initial registration of the Substance and thereby reduced of its own volition the possibility to respond to the assessment of ECHA. (Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 75)

Right to be heard on applications for permission to refer. As regards the documentary evidence of the data and cost-sharing negotiations, the right to be heard is respected if each party to a data and cost-sharing dispute is given the possibility to submit its own documentary evidence and its own arguments to ECHA during the course of the administrative procedure. (Decision of 17.11.2020, Case A-006-2019, *Sharda Europe*, para. 45; Decision of 17.12.2014 in Case A-017-2013, *Vanadium REACH Forschungs- und Entwicklungsverein*, para. 94-101)

Right to be heard in technical equivalence assessments (BPR). ECHA may take a decision rejecting or accepting an application for technical equivalence under Article 54(4) BPR only after giving the applicant the opportunity to submit comments on a draft decision. In order to comply with the right to be heard, a draft decision must cover the elements that lead ECHA to its draft conclusions on whether to reject or accept the application for technical equivalence. This is necessary to enable the applicant to submit comments on the draft decision that can correct an error or provide information that will argue in favour of the adoption or non-adoption of the final decision, or in favour of its having a specific content. (Decision of 24.11.2020, Case A-004-2019, *ARKEMA*, para. 55)

> ***Illustration***: ECHA referred to the need for information on respiratory irritation for the first time in the informal teleconference that took place after the draft decision had been notified to the appellant and only eight days before the expiry of the deadline granted to the appellant to submit comments on the draft decision. The appellant was placed in a position where it effectively had no opportunity to make known its views on the need for information on respiratory irritation before the adoption of the contested decision. Therefore, ECHA breached the right to good administration as it failed to respect the appellant's right to be heard. (Decision of 24.11.2020, Case A-004-2019, *ARKEMA*, para. 72-73)

7.1.3. Articles 50-51 REACH and beyond

Presumption of compliance. If ECHA follows the procedure set in place by the legislator in the evaluation title of the REACH Regulation, the right to be heard must normally be deemed

to have been respected. (Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 63; Decision of 21.10.2020, Case A-001-2019, *Solvay Fluor*, para. 112)

No right to comment on the revised draft decision under Articles 50-51 REACH. There is nothing in Articles 41 and 50(1) REACH to suggest that ECHA is required to invite registrants to comment on subsequent revised versions of a draft decision. Articles 51(2) and (5) REACH must be understood as giving the appellant the opportunity to comment on any proposals for amendment to the draft decision and not once more on the draft decision itself. (Decision of 07.10.2016, Case A-017-2014, *BASF*, para. 42 and 44; see also in relation to Article 51(5) REACH, Decision of 27.10.2015, Case A-006-2014, *International Flavors & Fragrances*, para. 117; see also in relation to Articles 41, 50(1), 51(1) and 51 (5) REACH, Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 59 ; Decision of 08.08.2018, Case A-009-2016, *Symrise*, para. 48; Decision of 21.10.2020, Case A-001-2019, *Solvay Fluor*, para. 113)

Right to comment on PfAs – new request. Where an element is included in proposals for amendment, registrants have a chance to comment on it. (Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 314)

Exceptional right to comment beyond Articles 50-51 REACH. In certain circumstances it is possible that the addressees of a decision should be given the opportunity to comment beyond the opportunities foreseen in Articles 50 and 51 REACH. (Decision of 12.07.2016, Case A-009-2014, *Albemarle Europe*, para. 225; Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 65 ; Decision of 08.08.2018, Case A-009-2016, *Symrise*, para. 53)

There may be a case for a new commenting round if during the decision-making process there is a major change in a decision imposing additional obligations on the addressees. Similarly, if relevant information comes to light during the decision-making process, ECHA may, depending for example on the relevance and importance of the new information, be required to re-start, or repeat certain steps of, the decision-making process. This might be necessary in some cases to ensure that all the relevant actors are given the opportunity to comment on that information, especially if this information has not been generated by the registrant itself. (Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 305-306; referring to Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 66-75 and Decision of 10.06.2015, Case A-001-2014, *CINIC Chemicals Europe*, para. 90)

> ***Illustration***. New elements included in the draft at the stage of the MSC meeting. (Decision of 08.08.2018, Case A-009-2016, *Symrise*, para. 75-78)
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> ***Illustration***. New elements included in a draft decision as revised following the registrant's comments. (Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 66-75)
>
> ***Illustration***. Information requirement (EOGRTS for reprotoxicity concern) beyond the scope of PfA (EOGRTS for ED concern). (Decision of 08.08.2018, Case A-009-2016, *Symrise*, para. 101)
>
> ***Illustration***. New data, added without commenting round, to an initial reasoning that was held to be too generic. (Decision of 08.08.2018, Case A-009-2016, *Symrise*, para. 101)

Consultation in separate process. The Endocrine Disruptor Expert Group is neither part of the substance evaluation decision-making procedure, nor the boarder substance evaluation process. Although the Endocrine Disruptor Expert Group provides informal scientific advice on the identification of endocrine disrupting properties of substances, decision-making under the substance evaluation process remains the responsibility of the competent authorities of the Member States and ECHA. The discussions at this meeting were therefore insufficient to ensure that the right to be heard was respected. (Decision of 08.08.2018, Case A-009-2016, *Symrise*, para. 101)

Cessation of manufacture or import. A registrant that has ceased the manufacture or import of a substance in accordance with Article 50(2) or (3) REACH cannot be requested to provide further information, unless the specific conditions set out in Article 50(4) REACH are fulfilled.

If a registrant ceases the manufacture or import of a substance, ECHA cannot start, or must discontinue if it has already started, a compliance check process under Article 41. (Decision of 09.11.2021, Case A-009-2020, *Polynt* [currently subject to appeal before the General Court], para. 38, 49)

Cessation of the manufacture after a compliance check decision. The follow-up process under Article 42(1) REACH is strictly limited to an assessment of whether the data-gaps identified in the initial compliance check decision have been filled. A follow-up compliance check decision does not contain a request for '*further information*' within the meaning of Article 41(3) as the relevant data-gaps have already been identified in the initial compliance check decision. A registrant that ceases the manufacture or import of a substance after being subject to a compliance check decision continues to be bound to provide the information requested in that decision. Such a cessation of manufacture only prevents the registrant from being subject to a new request concerning other information that was not requested in the initial compliance check decision. (Decision of 09.11.2021, Case A-009-2020, *Polynt* [currently subject to appeal before the General Court], para. 45, 49, 54)

> ***Illustration***. The appellant had ceased manufacturing the substance in question after being subject to an initial compliance check decision. ECHA did not err in finding in an Article 42(1) follow-up decision that the appellant continued to be bound to provide the information requested in the initial compliance check decision. The fact that the appellant had ceased the manufacture of the substance due to *force majeure*, and could no longer manufacture the substance, did not relieve the appellant from the obligation to provide the information requested in the initial compliance check decision, which was adopted before the cessation of manufacture of the substance (Decision of 09.11.2021, Case A-009-2020, *Polynt* [currently subject to appeal before the General Court], para. 49-56, 110-112)

7.2. Duty to state reasons

General. Under Article 130 REACH, ECHA must state reasons for all decisions it takes under the REACH Regulation. The duty to state reasons is an essential procedural requirement which is enshrined in the second paragraph of Article 296 TFEU and is included in Article 41(2)(c) of the Charter of Fundamental Rights of the EU as part of the right to good administration. (Decision of 29.06.2021, *SNF*, Case A-001-2020, para. 134; Decision of 09.11.2021, Case A-009-2020, *Polynt* [currently subject to appeal before the General Court], para. 89; Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 95)

A clear and unequivocal statement of reaIons is a necessary part of a decision of ECHA to enable the persons concerned to ascertain the reasons for the measure in question and to enable the BoA to exercise its power of review. (Decision of 29.06.2021, *SNF*, Case A-001-2020, para. 134; Decision of 27.10.2015, *International Flavors & Fragrances*, Case A-006-2014, para. 110)

The statement of reasons must be appropriate to the act at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the BoA to exercise its power of review. The requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations. (Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 127; Decision of 27.10.2015, Case A-006-2014, *International Flavors & Fragrances*, para. 110; Decision of 12.12.2017, Case A-013-2016, *BASF Personal Care and Nutrition*, para. 36-37; Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 137; Decision of 23.08.2022, Case A-004-2021, *Celanese Production Germany*, para. 98; Decision of 14.02.2023, Case A-012-2021, Covestro, para. 124; Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 96)

The duty to state reasons is an essential procedural requirement which must be distinguished from the question whether the reasoning is well founded, which is concerned with the

substantive legality of the measure at issue. (Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 113; Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 128; Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 139; Decision of 19.12.2016, Case A-018-2014, *BASF*, para. 217; Decision of 23.08.2022, Case A-004-2021, *Celanese Production Germany*, para. 106)

The requirements of the duty to state reasons can be attenuated if the measure in question was adopted in circumstances known to the affected person which enable it to understand the scope of the measure. (Decision of 19.12.2016, Case A-018-2014, *BASF*, para 218-220; Decision of 19.12.2016, Case A-018-2014, *BASF*, para. 218-220; Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others,* para. 130)

In light of the circumstances of a particular case, including its context and all legal rules applicable, it is not necessary for the reasoning in an ECHA decision to go into all the relevant facts and points of law, provided that the person concerned can understand the reasons for the decision and the BoA can exercise its powers of review. (Decision of 19.06.2013, Case A-001-2012, *Dow Benelux*, para. 87-88; Decision of 10.10.2013, Case A-004-2012, *Lanxess Deutschland*, para. 105; Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 104; Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 127; Decision of 27.10.2015, Case A-006-2014, *International Flavors & Fragrances*, para. 110; Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 172; Decision of 23.08.2022, Case A-004-2021, *Celanese Production Germany*, para. 99)

ECHA's duty to state reasons extends only to measures which adversely affect a person. (Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 106)

ECHA must provide an adequate statement of the reasons as to why the essential arguments put forward by a party cannot be upheld. (Decision of 12.12.2017, Case A-013-2016, *BASF Personal Care and Nutrition*, para. 70; Decision of 14.12.2021, A-007-2021, *Global Product Compliance (Europe)*, para. 28)

The adequacy of reasons given in a contested decision is assessed with reference to the context of that decision. The requirements of the duty to state reasons can be attenuated if the measure in question was adopted in circumstances known to the affected person which enable it to understand the scope of the measure. This is the case where a party was closely involved in the process by which the contested decision came about and is therefore aware of the reasons for which the administration adopted it. (Decision of 10.10.2013, Case A-004-2012, *Lanxess Deutschland*, para. 111; Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 105; Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 130; Decision of 27.10.2015, Case A-006-2014, *International Flavors & Fragrances*, para. 111; Decision of 23.08.2022, Case A-004-2021, *Celanese Production Germany*, para. 100)

Where an act of ECHA is adopted in direct and immediate consequence of the legislation, the level of justification required is more limited. (Decision of 10.10.2013, Case A-004-2012, *Lanxess Deutschland*, para. 109)

ECHA is not required to state reasons relating to an assessment, in this case of a weight of evidence, that it was not required to perform. (Decision of 01.08.2016, Case A-014-2014, *BASF Pigment*, para. 64; Decision 01.08.2016, Case A-003-2015, *BASF Pigment*, para. 70)

It is not necessary for the reasoning in an ECHA decision to go into all the relevant facts and points of law. In particular, ECHA is not required to adopt a position on all the arguments relied on by the parties concerned, but it is sufficient if it sets out the facts and the legal considerations having decisive importance in the context of the decision. The fact that ECHA did not specifically address in detail in the contested decision all the statements made by the third party does not mean that ECHA failed to take those statements into account. (Decision of 09.02.2021, Case A-015-2019, *Polynt*, para. 84)

Reasons not set out in the decision. A failure to state reasons cannot be remedied by the fact that the person concerned learns the reasons for the decision during the appeal proceedings. (Decision of 29.06.2020, *SNF*, Case A-001-2020, para. 138; Decision 07.03.2018, Case A-014-2016, *Solvay Solutions UK*, para. 70)

Several pillars of reasoning. Where some of the grounds of a contested decision provide a sufficient legal basis for a decision, any errors in the other grounds of the decision have no effect on its operative part. (Decision of 09.04.2014, Case A-001-2013, *Infineum UK*, para. 54)

The use of the word 'moreover' in the contested decision indicated a subsidiary argument. A plea challenging such subsidiary argument had been rejected as ineffective since it cannot call into question the primary justification for requesting an environmental exposure assessment and risk characterisation. (Decision of 28.06.2016, Case A-015-2014, *BASF*, para. 76)

Where some of the grounds in a decision on their own provide a sufficient legal basis for the decision, any errors in the other grounds of the decision have no effect on its operative part. Moreover, a plea which, even if well-founded, is incapable of bringing about the annulment which the appellant seeks must be rejected as ineffective. (Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 216)

Lack of reference to a precise legal basis. An indication of the legal basis is essential in the light of the obligation to state reasons that stems from Article 296 TFEU. That obligation must apply to all EU acts that produce legal effects. Failure to specify the precise legal basis need not necessarily constitute a material defect where it is possible to determine the legal basis for that act on the basis of other elements thereof. (Decision of 22.06.2021, *Tecnofluid*, Case A-002-2020, para. 42)

Lack of reference to a factsheet. The existence of a non-binding factsheet on the interface between REACH and the Cosmetics Regulation, even if referred to during a telephone conference with the appellant, does not satisfy the duty to state reasons for various reasons. These reasons include the fact that, if it had been covered by the decision-making procedure, Member States, who are responsible for enforcement, could have unanimously and expressly agreed to those reasons and the appellant would have been in a less legally uncertain position. In order for the appellant to be able to rely on it, or to contest it, the contested decision should have referred to it expressly. (Decision of 12.12.2017, Case A-013-2016, *BASF Personal Care and Nutrition*, para. 64-72)

Informal telephone conference. The minutes of the telephone conference state that *'[t]he communications made by [ECHA] during the telephone conference cannot be regarded as a formal opinion or position of [ECHA] concerning specific scientific or regulatory issues on the current draft decision.'* Therefore, information given during the telephone conference cannot be regarded as being part of the statement of reasons for the contested decision. In addition, any information given during the teleconference has not been formally agreed by the competent authorities of the Member States following the REACH procedure. (Decision of 12.12.2017, Case A-013-2016, *BASF Personal Care and Nutrition*, para. 69)

Operative part of a decision and statement of reasons. Due to the nature of ECHA's decisions, it is possible that the distinction between the binding and non-binding parts of an ECHA decision may not be absolute. As a result, obligations may also be found in Section III of a decision. (Decision of 12.07.2016, Case A-009-2014, *Albemarle Europe*, para. 132)

[While the statement of reasons required it,] the operative part of the contested decision did not oblige the appellant to carry out new studies in accordance with OECD Guidance Document No 36. If the appellant chose to carry out new studies, it would simply be required to follow a test method laid down in Commission Regulation (EC) No 440/2008 or another international test method recognised by the Commission or ECHA as being appropriate. (Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 136)

An inconsistency in the reasons of the contested decision as regards the threshold for identifying the degradation products did not lead to annulment of the contested decision. (Decision of 15.01.2019, Case A-004-2017, *3v Sigma*, para. 118)

7.3. Decision-making procedure (Articles 50-52 REACH)

Way of addressing registrant's comments. The contested decision was confusingly drafted insofar as its statement of reasons were not worded as a single and coherent analysis. The statement of reasons in the contested decision repeated first the text of the initial draft decision and then added text relating to the appellant's comments and ECHA's assessment of those comments. It was possible that this way of drafting the contested decision may have given the appellant the impression that some of its comments were not taken into account. However, this did not call into question the legality of the contested decision. (Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 53)

Absence of PfA. The BoA observed that the fact that the MSCAs did not propose any amendments relating to sub-chronic toxicity and pre-natal developmental toxicity demonstrates, if anything, that the MSCAs agreed with the content of the revised draft decision as far as these two endpoints are concerned. (Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 51)

PfA by ECHA under substance evaluation. The provisions of Article 51(2) to (8) REACH apply *mutatis mutandis* to the adoption of the final substance evaluation decision. In particular, ECHA and MSCAs may submit PfAs which will then be shared with the concerned registrants or downstream users for their comments. (Decision of 07.12.2016, Case A-013-2014; *BASF*, para. 66; Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 183-187)

Consideration of PfA by MSC not expressly mentioned in decision. Whilst the fact that the PfA was taken into account was not made explicit in the contested decision, it was known by the appellant who attended the MSC meeting, as explained in ECHA's defence and not contested by the appellant. Therefore, the BoA considered that Articles 50(1) and 51(5) REACH were not breached. (Decision of 07.10.2016, Case A-017-2014, *BASF*, para. 64)

Modification of draft decision during MSC meeting. As long as the procedural provisions and safeguards have been respected, the MSC may modify ECHA's draft decision prior to reaching unanimous agreement. (Decision of 19.06.2013, Case A-001-2012, *Dow Benelux*, para. 69)

Allegedly insufficient time for MSC to decide. Although the time allowed to the MSC to consider the appellants' comments on the proposals for amendment was short, the MSC was nonetheless given the opportunity to consider those comments. No Member State indicated during the written procedure that they did not have sufficient time to consider these comments. (Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 322)

Adoption via written procedure. There is no requirement under the REACH Regulation for a draft decision to be discussed orally at an MSC meeting. (Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 173)

Participation of a registrant in an MSC meeting. ECHA has not failed to safeguard the procedural rights of a registrant where, despite the fact that the registrant did not participate in the MSC meeting, all steps of the procedure have been properly undertaken. Registrants' participation in MSC meetings is not prescribed by the REACH regulation, wherefore it is at the discretion of the MSC to decide whether it is appropriate; the fact that such participation did not occur does not constitute an infringement of procedural rights. (Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 127; Decision of 08.08.2018, Case A-009-2016, *Symrise*, para. 49; Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 317 and 323-324)

Late request for extension of commenting period. ECHA was not obliged to grant the appellant's request for an extension of the deadline for commenting on the proposals for amendment as the appellant submitted its extension request after the expiry of the deadline. (Decision of 08.08.2018, Case A-009-2016, *Symrise*, para. 50)

New information at the MSC meeting. The results of a certain study were introduced for the first time at the MSC meeting. However, ECHA did not take into consideration data on an in vitro comet assay introduced by the appellants at the same MSC meeting. The contested decisions do not explain why documents introduced at a similar stage of the decision-making procedure were treated differently. (Decision of 10.02.2020, Joined Cases A-003-2018, A-004-2018 and A-005-2018, *BASF and Others*, para. 109)

Addressee and downstream users 'concerned'. The term 'concerned' in Article 50 REACH refers to registrants or downstream users insofar as they are recipients of a draft decision under the compliance check, testing proposal or substance evaluation procedures. Downstream users have procedural rights if they are a 'concerned' registrant or downstream user. (Decision of 30.05.2017, Case A-022-2015, *Michelin*, para. 86)

'Concerned registrants'. The concerned registrants to be notified in the course of a compliance check within the meaning of Article 50(1) REACH are only the registrants of the particular substance subject to a draft decision and not the registrants of another substance, even in case of read-across to data on the other substance. (Intervention Decision of 15.12.2017, Case A-006-2017, *Climax Molybdenum (Plansee)*, para. 15-20; Intervention Decision of 15.12.2017, Case A-006-2017, *Climax Molybdenum (Sadaci)*, para. 15-20)

Informal discussions. Within a timeframe of 30 days following the end of the 30-day timeline prescribed to provide comments on the draft decision in Article 50(1) REACH, ECHA can invite the appellant to an informal dialogue to discuss several issues related to the draft decision (e.g. the scientific rationale of the decision). However, the appellant's decision not to use the possibility to have such an informal dialogue did not oblige ECHA to raise on its own motion the issues that ECHA could have clarified in such dialogue. (Decision of 29.04.2021, Case A-014-2019, *LG Chem Europe*, para. 54, 56-58)

8. REACH - GENERAL

8.1. Rules of interpretation

General. In interpreting provisions of EU law, their wording, context and objectives must all be taken into account (*ex multis* Decision of 25.04.2023, Joined Cases A-002-2022 and A-003-2022, *BASF Lampertheim*, para. 38)

The BoA is competent to take a position on the interpretation of the REACH Regulation insofar as ECHA is competent to apply it (Decision of 12.12.2017, Case A-013-2016, *BASF Personal Care and Nutrition*, para. 47-51; Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum*, para. 124)

In claris no43nterpretationetatio. There is in principle no need for interpretation of a provision, particularly in light of its context and purpose, when its scope can be determined with precision on the basis of its wording alone, the clear text being sufficient in itself. The BoA adopted a literal interpretation of the definition of intermediate, rejecting counter-arguments as being unsupported by the letter and spirit of REACH as well as the economic reality of the relevant sector. (Decision of 25.05.2016, Case A-010-2014, *Nordenhamer Zinkhütte*, para. 39-49 and 60; Decision of 02.03.2017, Case A-011-2014, *Huntsman P&A UK*, para. 60-69)

Strict interpretation. Exceptions must be interpreted strictly. (Decision of 06.08.2018, *SI Group UK and Others*, Case A-006-2016, para. 64)

8.2. Objectives of the REACH Regulation

The REACH Regulation, as is clear from Article 1 thereof, aims to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. Importantly, regard being had to Recital 16 REACH, the Community legislature established the first of those three objectives, namely to ensure a high level of protection of human health and the environment, as the main purpose of the REACH Regulation. (Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 39; Decision of 27.10.2015, Case A-006-2014, *International Flavors & Fragrances*, para. 44)

The protection of the environment constitutes one of the primary objectives of the REACH Regulation and takes precedence over economic considerations. The importance of the objectives pursued may justify substantial negative economic consequences for certain operators. (Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 81)

The main objective of the information requirements for registration is to achieve a high level of protection of human health and the environment. However, that main objective is not in itself sufficient to justify an interpretation that goes against the wording and context of a provision. (Decision of 25.04.2023, Joined Cases A-002-2022 and A-003-2022, *BASF Lampertheim*, para. 48)

8.3. Definitions

Substances and mixtures. The BoA examined, in the circumstances of a case in which doubts arose whether a registration had been submitted which contained more than one substance subject to registration, what is a substance and what is a mixture. (Decision of 02.04.2014, Case A-008-2012, *PPH Utex*, para. 38-43)

Each registration dossier must relate to a single substance. Two different substances cannot be registered in the same dossier regardless of whether they present the same hazard properties. (Decision of 02.04.2014, Case A-008-2012, *PPH Utex*, para. 45)

The decision on which substance or substances to register lies with the manufacturer or importer concerned. Where a dossier contains more than one substance, ECHA cannot unilaterally dictate which of those substances should be the subject of registration. (Decision

of 02.04.2014, Case A-008-2012, *PPH Utex*, para. 47, 54 and 61; Decision of 02.03.2017, Case A-011-2014, *Huntsman P&A UK*, para. 48)

It is of utmost importance that a registrant unambiguously identifies the substance it is intending to register. (Decision of 09.04.2014, Case A-001-2013, *Infineum UK*, para. 67 and 72; Decision of 02.03.2017, Case A-011-2014, *Huntsman P&A UK*, para. 48)

A registrant is at liberty to give a broad definition of the substance which it intends to register, for example by including both the bulk forms and the nanoforms of various crystal phases of the substance in question. If a registrant gives a broad definition of its substance, however, the hazards posed by all possible forms of the substance covered by the substance definition must be addressed by the toxicological and ecotoxicological information provided in the registration dossier. (Decision of 02.03.2017, Case A-011-2014, *Huntsman P&A UK*, para. 49)

UVCB substances. When a registrant provides information on the identity of the substance it is intending to register, as a general principle all constituents need to be identified as far as it is possible and reasonable to do so, accepting that with UVCB substances it is often the case that not all constituents of the substance can be identified. More specifically, any constituent present at 10% or more must be identified. The 10% threshold does not mean that any constituent that is present below this threshold does not need to be identified. It should be rather interpreted that constituents below this threshold should also be identified as far as it is possible and reasonable to do so. In addition, it is clear from the guidance that ECHA requires that any constituents that are relevant for classification shall also be identified. It is the clear responsibility of the registrant to identify the substance it is intending to register as far as it is reasonably possible to do so and consistent with the REACH Regulation. (Decision of 09.04.2014, Case A-001-2013, *Infineum UK*, para. 67 and 72)

ECHA was not bound by law or previous practice to require testing on constituents of the substance only if the constituent in question exceeded 0.1% w/w. Annex XIII REACH does not provide specific rules relating to the identification of the PBT/vPvB properties of UVCBs where the exact composition is unknown or variable and which contain different constituents. It is for ECHA, acting within its margin of discretion, to identify the appropriate method for the identification of PBT/vPvB properties on a case-by-case basis, in light of the objectives of the REACH Regulation, and after examining, carefully and impartially, and taking into consideration, all the relevant facts and circumstances of the individual case. (Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 62)

Stabiliser. The concept of stabiliser within the meaning of the REACH Regulation does not extend only to the chemical but also to the physical stability of a substance. (Decision of 09.04.2014, Case A-001-2013, *Infineum UK*, para. 42)

Lubricating oil could be considered primarily an additive whose function is to ensure the stability of the relevant substance, as it constituted a necessary part of the manufacturing process of the substance itself and was not added mainly to ensure stability. (Decision of 09.04.2014, Case A-001-2013, *Infineum UK*, para. 48 and 52)

Intermediate*.* There are two clear requirements that need to be met cumulatively in order for a substance to qualify as an intermediate: (i) the substance must be manufactured for, and consumed in, a chemical process and (ii) there must be an intentional transformation of the substance into another substance in that chemical process. The main aim of the use of the substance is irrelevant. (Decision of 25.05.2016, Case A-010-2014, *Nordenhamer Zinkhütte*, para. 41-42)

The relevant process to be taken into account is not the entire production process but the chemical reaction of the substance with the raw materials. The intent to transform can be derived from deliberate modification to the design of the plant. Intentional transformation excludes incidental transformation into another substance and situations where the transformation is the end-use of the substance, such as a sealing function, or where the substance merely help in the transformation. It is irrelevant whether the resulting substance is the only substance produced in a plant, the main substance of the plant in terms of revenue or

quantity, a by-product or just one of the many substances produced in the plant. (Decision of 25.05.2016, Case A-010-2014, *Nordenhamer Zinkhütte*, para. 52-57, 59 and 64)

'Assenting registrants' under Article 11(1) REACH. The second subparagraph of Article 11(1) REACH, read in conjunction with Article 10(a)(ix) REACH, provides that testing proposals must be submitted by the lead registrant for a substance not only on its own behalf, but also on behalf of the '*assenting registrants*'. The term '*assenting registrants*' must be read in light of Article 11(3) REACH, which provides that registrants may only submit information (and testing proposals) separately by doing so expressly in their registration dossiers, and only for specific reasons. Registrants of a substance to whom an information requirement applies and whose lead registrant submits a testing proposal to ECHA are therefore deemed to have assented to that testing proposal unless they have decided to submit information separately in accordance with Article 11(3) REACH. (Decision of 23.02.2021, Joined Cases A-016-2019 to A-029-2019, *Lubrizol France and Others,* para. 157-158)

8.4. Relationship with other legislation and/or other bodies

Cosmetics Regulation (Regulation (EC) No 1223/2009). The REACH Regulation and the Cosmetics Regulation have similar objectives and may apply to the same substance. When interpreting and applying the REACH Regulation, account must be taken of related acts such as the Cosmetics Regulation. (Decision of 12.12.2017, Case A-013-2016, *BASF Personal Care and Nutrition*, para. 54)

ECHA is not competent to apply or implement Article 18(1)(b) of the Cosmetics Regulation. It is not competent to give a binding interpretation of this provision. ECHA must, however, be able to take a position on the interpretation of that provision insofar as this is necessary in order to interpret and apply the REACH Regulation (see Articles 2(4)(b), 2(6)(b), 14(5)(b), 56(5)(a) and 67(2) REACH). (Decision of 12.12.2017, Case A-013-2016, *BASF Personal Care and Nutrition*, para. 47-51)

The testing and marketing bans in the Cosmetics Regulation do not prevent registrants of a substance used, exclusively or amongst other uses, as an ingredient in cosmetic products from carrying out studies on vertebrate animals pursuant to the information requirements in the REACH Regulation. The REACH Regulation contains no provision that exempts registrants from the requirement to carry out studies on vertebrate animals only because the substance is used as an ingredient in cosmetic products. In order to benefit from an exemption, registrants of a substance used as an ingredient in cosmetic products must establish that the conditions for an adaptation under Section 3 of Annex XI REACH in conjunction with Article 14(5)(b) REACH are fulfilled. This conclusion is not called into question by the Cosmetics Regulation. (Decision of 18.08.2020, Case A-009-2018, *Symrise*, para. 116-117; Decision of 18.08.2020, Case A-010-2018, *Symrise*, para. 117-118)

Conflict of opinion with other EU bodies (Art. 95 REACH). In its evaluation under the General Food Law Regulation [Regulation (EC) No 178/2002], European Food Safety Authority (EFSA) assessed the risk posed by benzaldehyde when used as a food flavouring. Based on this assessment, EFSA concluded that benzaldehyde does not pose a risk to consumers at the estimated levels of intake as a food flavouring. An EFSA finding that there is no such risk does not mean that the evaluated substance does not present any (other) concern to human health or to the environment or presuppose an overall analysis of the intrinsic properties of the substance. In the compliance check decision-making procedure leading to the contested decision, ECHA did not assess the risks that exposure to benzaldehyde poses to human health and to the environment. ECHA found that the lead registrant's dossier did not fulfil the information requirements set out in the testing Annexes as the proposed read-across adaptations did not comply with Section 1.5. of Annex XI REACH. Therefore, there was no conflict of opinion between ECHA and EFSA that required ECHA to take action under Article 95 REACH before adopting the contested decision. (Decision of 24.03.2020, Case A-006-2018, *Emerald Kalama Chemical and Others*, para. 90 to 94)

Implementing acts. No implementing act could amend or supplement ECHA's powers to verify compliance with Article 11 under the completeness check process if those powers were

not already provided for in the REACH Regulation. (Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 123)

OECD test guidelines. OECD TG 305 is not a legally binding piece of legislation that could be 'breached' by ECHA. (Decision of 07.12.2016, Case A-013-2014, *BASF*, para. 122)

OECD decision on the mutual acceptance of data (MAD). The MAD decision is not in itself binding on ECHA. Even assuming that ECHA would be bound by the MAD decision, ECHA would in any event have been entitled to conclude that the study in question was not performed correctly. (Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum*, para. 95-98)

The MAD system is not binding on the Agency as the European Union has not acceded to the Convention on the OECD, nor adhered to the MAD Decision. (Decision of 06.06.2023, Cytec Engineered Materials, Case A-001-2022, para. 52)

OECD review programme. The mere fact that a study was relied on under the OECD Cooperative Chemicals Assessment Programme did not provide any information concerning whether that study complies with Column 1 of Section 8.7.2. of Annex IX REACH. (Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum*, para. 104)

Directive 2010/63/EU on the protection of animals used for scientific purposes. When satisfying the information requirement the appellant still has to apply the relevant provisions in the REACH Regulation and to abide by the applicable animal welfare rules, such as instruments transposing Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes. (Decision of 19.12.2016, Case A-018-2014, *BASF*, para. 121)

9. REACH – REGISTRATION

Completeness check. ECHA must ascertain that all the elements required under Article 20(2) REACH are provided in a registration dossier, which does not constitute an assessment of the quality of the adequacy of any information submitted. (Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 107)

The fact that the IT application used by ECHA cannot verify the presence of all the elements required under Articles 10 and 12 REACH does not exonerate ECHA from its obligation to check the completeness of dossiers in accordance with Article 20(2) REACH. (Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 105-106)

It is within ECHA's discretion to carry out the completeness check at any point within the three months granted to it under the second subparagraph of Article 20(2) REACH, regardless of whether there is a pending data sharing dispute. (Decision of 03.12.2014, Case A-005-2013, *Vanadium* (I), para. 60)

Principle of 'one substance, one registration'. If there are several registrants of a substance, they are required to submit data jointly. Any disagreement with the lead registrant regarding the selection or cost of the relevant information should be addressed either during data sharing negotiations, with the ensuing possibility to seek permission to refer from ECHA, or by way of an 'opt-out' pursuant to Article 11(3) REACH. (Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 76-77)

Any subsequent registrants of the same substance must identify, inter alia, the lead registrant in their registration dossier based on Article 10(a)(i) and Section 1.2 of Annex VI REACH. Under Article 20 REACH registrants can and should be prevented from submitting registration dossiers which are not part of an existing registration for the same substance. (Decision of 15.03.2016, Case A-022-2013, *REACHeck Solutions*, para. 119-120)

If ECHA finds, after a registration number has been granted, that a registration is incomplete as it is not part of a joint registration, under Article 20 REACH the registrant concerned must be given a reasonable period to complete its registration by joining the joint submission or otherwise justify why it should not be part of the joint submission. ECHA must then perform a further completeness check, considering the information submitted by the registrant. If the registrant fails to complete its registration, for example by failing to join the joint registration, ECHA must take a decision pursuant to Article 20(2) REACH rejecting the registration. This decision would be appealable to the BoA. (Decision of 29.01.2019, Case A-005-2017, *Thor*, para. 67-68)

Articles 20 and 41 REACH are the only provisions in the REACH Regulation which allow ECHA to verify that a registrant has respected the principle of one substance, one registration. (Decision of 29.01.2019, Case A-005-2017, *Thor*, para. 77)

Different substances with the same EC number. At the time of adoption of the contested decision, one of the registrants described the substance as a UVCB and the other one as multi-constituent substance. It was therefore not clear that the two registrants had in fact registered the same substance, despite the fact that they had used the same EC identifier. It was therefore not clear that, at the time of adoption of the contested decision, the appellant had failed to meet its joint submission obligation. (Decision of 29.01.2019, Case A-005-2017, *Thor*, para. 85)

Complete opt-out and token. Article 11 REACH clearly covers the situation whereby a registrant relies on a complete opt-out for registration purposes. There is no need for a 'joint submission dispute' and consequently no need to put in place a procedure to resolve differences between the lead registrant and another registrant over the provision of a 'token' if the other registrant relies on a complete opt-out for registration purposes. There is also no such provision in the REACH Regulation. In practice, since ECHA has implemented Article 11 REACH by means of an information technology system requiring the use of a 'token', ECHA must, when requested, give the 'token' to any registrant who informs it of its decision to rely on a complete

opt-out in accordance with Article 11(3) REACH. (Decision 23.03.2018, Case A-011-2017, *REACheck Solutions*, para 42-44, 59-66)

Abrogation of a completeness check decision (following SME verification). It is a general principle of European Union law that a body which has the power to adopt a particular legal measure also has, in principle, the power to abrogate or amend an initial decision that is contradicted. (Decision of 28.02.2023, Case A-013-2021, *Gruberchem*, para. 38; Decision of 28.02.2023, Case A-014-2021, *Gruberchem*, para. 38)

The exercise of this Iower is subject to several conditions. (1) There must be a new fact which the Agency has the power to verify, and which justifies the abrogation of the initial decision that is contradicted by this new fact. A re-assessment of information already submitted during the initial completeness check is not sufficient. (2) The power must not be reserved to another body. In particular, the Agency's decision must not constitute a sanction or penalty, as the power to impose sanctions or penalties is reserved to the Member States under Article 126 of the REACH Regulation. (3) The Agency must apply mutatis mutandis the procedure which is foreseen for the adoption of that decision (parallelism of form). (4) The Agency must comply with the general principles of European Union law, in particular the principle of the protection of legitimate expectations. (Decision of 28.02.2023, Case A-013-2021, *Gruberchem*, para. 64-98; Decision of 28.02.2023, Case A-014-2021, *Gruberchem*, para. 64-98)

10. REACH – DATA-SHARING

10.1. General

General. Article 30(3) REACH sets out obligations for the sharing of data and costs within a SIEF both before and after a substance has been registered by the first registrant(s). The condition that applies after a substance has been registered by the first registrant(s) is set out in the fourth sentence of Article 30(3) REACH. If the information has already been submitted to ECHA in a dossier of a previous registrant, ECHA can grant a potential registrant of the same substance permission to refer to this information. (Decision of 21.09.2020, Case A-023-2018, *Oxiteno Europe*, para. 49-50)

The obligation for a registrant to submit its registration dossier is not subject to any prior authorisation from ECHA regardless of whether a data sharing dispute is pending. The obligation to submit a registration dossier stems directly from the REACH Regulation. (Decision of 03.12.2014, Case A-005-2013, *Vanadium* (I), para. 46)

Article 30(3) REACH sets out obligations for the sharing of data and costs within a SIEF both before and after a substance has been registered by the first registrant(s). The condition that applies after a substance has been registered by the first registrant(s) is set out in the fourth sentence of Article 30(3) REACH. If the information has already been submitted to ECHA in a dossier of a previous registrant, ECHA can grant a potential registrant of the same substance permission to refer to this information. (Decision of 21.09.2020, Case A-023-2018, *Oxiteno Europe*, para. 49-50; Decision of 27.10.2020, Case A-024-2018, *Symrise*, para. 74-76)

In its assessment of whether every effort had been made, ECHA cannot take into consideration arguments or justifications that were not made during those negotiations. The task of ECHA in a data sharing dispute entails examining the records of the negotiations, and the arguments presented therein, as provided by the parties to that dispute. ECHA's assessment of whether every effort is made is wholly based on the exchanges of information between the two parties. (Decision of 17.12.2014, Case A-017-2013, *Vanadium* (II), para. 56, 99)

ECHA's assessment must be carried out on the basis of the negotiations as a whole, and should centre on those elements on which the parties could not agree during their negotiations, and which therefore led to the filing of the application for permission to refer. (Decision of 21.09.2020, Case A-023-2018, *Oxiteno Europe*, para. 87 ff.)

Powers of ECHA. Neither Article 30(3) REACH nor Article 4(1) of Implementing Regulation 2019/1692 contain rules concerning the admissibility of applications for permission to refer. Under those provisions, ECHA may only grant an application for permission to refer if the relevant conditions are fulfilled, or reject the application if they are not. (Decision of 22.06.2021, *Tecnofluid*, Case A-002-2020, para. 46)

Applicability of Article 30 REACH in case of negotiations conducted between 1 June 2018 and 31 December 2019. Neither the REACH Regulation nor Implementing Regulation 2019/1692 make the granting of a permission to refer under Article 30(3) REACH conditional on data and cost-sharing negotiations taking place before 1 June 2018. The data-sharing rules in Articles 26 and 27 REACH apply to (potential) registrants who have pre-registered a phase-in substance under Article 28 REACH, only after the cut-off date of 31 December 2019. (Decision of 22.06.2021, *Tecnofluid*, Case A-002-2020, para. 51-55)

10.2. Criteria for granting an application for permission to refer

Test. In light of Article 5 of Implementing Regulation 2016/9, ECHA is required to grant a potential registrant permission to refer if, despite the potential registrant's requests and objections, the previous registrant fails to comply with the requirements for data and cost-sharing to be transparent, fair and non-discriminatory. (Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 51-56, 76-83, 174 and 175; Decision of 23.07.2020, Case A-013-2018, *Tecnofluid (I)*, para. 29; Decision of 23.07.2020, Joined Cases A-014-2018 to A-021-2018, *Tecnofluid (II)*, para. 41; Decision of 27.10.2020, Case A-

024-2018, *Symrise*, para. 106; Decision of 21.09.2020, Case A-023-2018, *Oxiteno Europe*, para. 94; Decision of 15.12.2020, Case A-005-2019, *Codyeco and Others*, para. 34)

The examination of the requirements for sharing data and costs must be carried out in a logical sequence. First, it is necessary to assess whether the previous registrant has been transparent and whether the terms it proposes are therefore clear and comprehensible. If so, it is then possible to examine whether the terms proposed by the previous registrant are fair and non-discriminatory. (Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 85; Decision of 21.09.2020, Case A-023-2018, *Oxiteno Europe*, para. 95 ff.; Decision of 23.07.2020, Case A-013-2018, Tecnofluid (I), para. 33)

No 'balancing of efforts'. ECHA's assessment must be balanced in the sense that it must be carried out on the basis of the negotiations as a whole, taking into account the actions of both parties to the negotiations and all other relevant circumstances. ECHA must have due regard to all the individual actions and communications of the parties as well as the development of the negotiations over time (Decision 29.05.2018, Case A-007-2016, *Sharda Europe,* para. 59; Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 86, 87; Decision of 23.07.2020, Joined Cases A-014-2018 to A-021-2018, *Tecnofluid (II)*, para. 91)

These findings do not mean that ECHA is to 'balance' the parties' efforts against each other. These findings refer to the case-law of the EU Courts according to which, when exercising its discretion, ECHA must examine carefully and impartially all the relevant aspects of an individual case. If a previous registrant fails to comply with the requirements for data and cost-sharing to be transparent, fair and non-discriminatory, ECHA should not 'balance' that failing against other considerations, such as whether the potential registrant had 'a real intention to find an agreement'. (Decision of 23.07.2020, Joined Cases A-014-2018 to A-021-2018, *Tecnofluid (II)*, para. 90-93)

Time of filing the application. The time at which an application for permission to refer should be lodged with ECHA and the amount of time that parties should invest in negotiating the sharing of data is entirely dependent on the facts in the particular case. (Decision of 17.12.2014, Case A-017-2013, *Vanadium* (II), para. 113)

Difference between assessing and imposing a calculation method or amount payable. It is not for ECHA to prescribe how costs should be calculated or shared in a particular case. This does not mean, however, that ECHA cannot assess whether the proposed terms for calculating and sharing costs are fair, transparent and non-discriminatory. (Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 58)

The competence to determine what the equal sharing of costs means in practice, as well as to assess the amount to be paid by a data claimant, falls within the jurisdiction of national courts. (Decision of 21.09.2020, Case A-023-2018, *Oxiteno Europe*, para. 59 ff.)

Application for permission to refer to a study in case of an opt-out. The BoA rejected the claim that ECHA would not be competent under Article 30(3) REACH when data sharing negotiations concern reference to a study in order to submit a registration dossier as an opt-out under Article 11(3) REACH. The obligation to share data and costs is always applicable when a registrant seeks access to a study that it requires for its registration dossier. (Decision of 27.10.2020, A-024-2018, Symrise, para 65-81)

List of studies. Before permission to refer is actually granted it is the duty of ECHA to clarify the individual relevant studies to which access is sought. In particular, a definitive list of the studies requested is necessary to ensure that access, if granted, is only given to the data required to cover a claimant's registration requirements. In this respect, it is also important to note that, pursuant to Article 30(3) REACH, permission to refer can only be granted to studies involving vertebrate animals and not to other data that may have been part of the initial negotiations. (Decision of 17.12.2014, Case A-017-2013, *Vanadium* (II), para. 74)

10.2.1. Transparency

Definition. In order to comply with the requirement for data and cost-sharing to be transparent, a previous registrant must provide, upon request from a potential registrant, clear and comprehensible explanations as to (i) which information is to be shared, (ii) how the cost of generating the information is determined, (iii) how the cost of gathering and submitting the information to ECHA is determined, and (iv) how costs are to be shared among registrants. (Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 77 and 78; Decision of 21.09.2020, Case A-023-2018, *Oxiteno Europe*, para. 97; Decision of 23.07.2020, Case A-013-2018, T*ecnofluid (I)*, para. 34; Joined Cases A-014-2018 to A-021-2018, *Tecnofluid (II)*, para. 46; Decision of 27.10.2020, Case A-024-2018, *Symrise*, para. 115; Case A-005-2019, *Codyeco and Others*, para. 35)

Concretisation by Article 2 of Implementing Regulation 2016/9. Article 2(1)(a) and (2) Implementing Regulation 2016/9 requires a previous registrant to provide a potential registrant, on request, with '[an] itemisation of data to be shared, including the cost of each data item, a description indicating the information requirements in the REACH Regulation to which each cost corresponds and a justification of how the data to be shared satisfies the information requirement'. The previous registrants were therefore required to provide the potential registrants with a complete list of the available information relevant for the registration of the substances in question. (Decision of 23.07.2020, Joined Cases A-014-2018 to A-021-2018, *Tecnofluid (II)*, para. 47; Decision of 15 December 2020, Case A-005-2019, *Codyeco and Others*, para. 44)

The itemisation of data and costs concerns only the nature of the information available for the registration of a substance, and the cost of that information. The itemisation of data and costs does not depend on the identity, or even the number, of potential registrants of a substance. A request made by the representative of the potential registrants was sufficient to trigger the previous registrant's leading registrant's obligation under the Articles 2(1) and (2) Implementing Regulation 2016/9 Decision to provide an itemisation of data and costs. (Decision of 15.12.2020, Case 005-2019, *Codyeco and Others*, para. 45-48)

The titles and authors of studies are essential to allow a potential registrant to determine whether it needs to obtain permission to refer to those studies. (Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 95-96)

The term '*itemisation*' implies the precise identification of each piece of information in a list. In the case of scientific studies an '*itemisation*' must therefore include the title and authors of each study. (Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 97; Decision of 23.07.2020, Joined Cases A-014-2018 to A-021-2018, *Tecnofluid (II)*, para. 46-47)

> ***Illustration***. An unjustified requirement to pay a lump sum before beginning negotiations. (Decision of 27.10.2020, A-024-2018, *Symrise*, para 119-120)

10.2.2. Fairness

Definition. In order to comply with the requirements for data and cost-sharing to be fair, a previous registrant can only require a potential registrant to pay a share of the costs of generating, gathering and submitting to ECHA the information that the potential registrant requires for the purposes of its own registration. These costs must moreover be actual in the sense that they can be determined either by proof or by approximation. (Decision of 23.07.2020, Case A-013-2018, Tecnofluid (I), para. 36; Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 79-81)

> ***Illustration***. An annual surcharge calculated according to the interest rates in Directive 2000/35/EC is entirely unrelated to the actual costs of generating, gathering and submitting information to ECHA for the purposes of a registration under the REACH Regulation. (Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 130)

Illustration. Costs of managing a consortium of which the applicant for permission to refer is not a member must not be included in the calculation. (Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 111)

Illustration. Costs relating to studies which are not required for the registration of the substance by the applicant for permission to refer. (Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 112-114)

Illustration. An annual surcharge of 15%. (Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 161-163)

Reimbursement clauses. A system whereby the costs borne by each registrant of a particular substance are subsequently adjusted to take into account the eventual number and level of registrations may, in certain circumstances, be considered to be an important point in assessing whether every effort had been made. (Decision of 17.12.2014, Case A-017-2013, *Vanadium* (II), para. 53)

An existing registrant is not entitled to impose unilaterally the exclusion of a reimbursement mechanism. If a data claimant refuses such an exclusion, it cannot be seen as the cause of the failure of the negotiations. (Decision of 27.10.2020, A-024-2018, *Symrise*, para 109-112)

Costs incurred before the entry into force of Implementing Regulation 2016/9. Costs incurred before the entry into force of Implementing Regulation 2016/9, including administrative costs, can be determined either by proof or by approximation. (Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 189; Decision of 21.09.2020, Case A-023-2018, *Oxiteno Europe*, para. 69)

10.2.3. Non-discrimination

Definition. In order to comply with the requirements for data and cost-sharing to be non-discriminatory, registrants that are in comparable situations must not be treated differently and registrants who are in different situations must not be treated in the same way unless such treatment is objectively justified. (Decision of 23.07.2020, Case A-013-2018, *Tecnofluid (I)*, para. 39; Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 82-83)

All SIEF participants are in a comparable situation in so far as they have to submit information for registration purposes and are subject to the same rules and obligations for the sharing of data and costs. (Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 134; Decision of 17.12.2014, Case A-017-2013, *Vanadium* (II), para. 46)

Pursuant to Articles 3(9) and (11), and 6(1) REACH, each natural or legal person who manufactures or imports a substance in quantities above one tonne per year is required to submit its own registration for that substance to ECHA. This also applies to legal persons which are affiliates of another registrant of the same substance. Moreover, pursuant to the first subparagraph of Article 4(2) of Implementing Regulation 2016/9, the terms for data and cost-sharing for a substance must apply to all registrants of that substance, including the possibility of future registrants joining at a later stage. These provisions demonstrate that all present and future registrants of a substance are in a comparable situation as regards data and cost-sharing. (Decision of 23.07.2020, Case A-013-2018, *Tecnofluid (I)*, para. 41-46; Decision of 23.07.2020, Joined Cases A-014-2018 to A-021-2018, *Tecnofluid (II)*, para. 64-69; Decision of 27.10.2020, Case A-024-2018, *Symrise*, para. 123-127)

Illustration. An annual surcharge benefitted the early registrants of a substance as they obtained cumulatively a share of the surcharge paid by all later registrants, whereas the later registrants only get a share of the surcharge from the even later registrants but not from the previous registrants. Ultimately, all other things being equal, the price in real terms of a letter of access would be higher for later registrants than earlier ones. (Decision of 15.04.2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, para. 139)

Illustration. A general and absolute exemption of affiliates from the requirement to pay a share of costs constituted a different treatment of registrants that are in comparable situation. In the absence of a case/specific justification, it infringed the requirement of the data and cost-sharing to be non-discriminatory. (Decision of 23.07.2020, Case A-013-2018, *Tecnofluid* (I), para. 41-46; Decision of 23.07.2020, Joined Cases A-014-2018 to A-021-2018, *Tecnofluid* (II), para. 64-69; Decision of 27.10.2020, Case A-024-2018, *Symrise*, para. 123-127)

11. REACH – INFORMATION REQUIREMENTS

11.1. General

Substance definition and information requirements. If a registrant chooses to give a broad definition of the substance for the purposes of registration means that it is required to submit, inter alia, information concerning the toxicological and ecotoxicological properties for the entirety of the substance covered by this broad definition. The procedures available to ECHA in the REACH Regulation allow for this information, and potentially other information on the substance, to be considered to ensure that sufficient information is available regarding the hazards and risks posed by the substance. (Decision of 02.03.2017, Case A-011-2014, *Huntsman P&A UK*, para. 71-72)

Exposure and intrinsic properties. The levels and patterns of exposure to a substance may vary over time, depending for example on the uses of a substance, whilst the intrinsic properties of a substance remain the same. It is therefore necessary, for the purposes of the REACH Regulation, that information on the intrinsic properties of a substance should be generated independently from information on the levels of exposure to that substance, so as to allow regulators, manufacturers and importers to determine the risk posed by a substance at any given moment in time. This, in turn, is essential in order to attain the main objective of the REACH Regulation, which is to achieve a high level of protection of human health and the environment. (Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum*, para. 133-135)

In principle, the REACH Regulation requires registrants to submit information on the intrinsic properties of a substance in accordance with Annexes VII to X even if, based on its current uses, the substance can be shown to pose no risk due to limited, or no, exposure to that substance. The levels and patterns of exposure to a substance may vary over time depending, for example, on the uses of that substance, whilst the intrinsic properties of a substance, once they are identified, notably as they result from the information requirements set out in Annexes VII to X, remain the same. In addition, where a substance has several registrants, uses and exposure may vary from one registrant to another whilst the intrinsic properties of that substance are the same for all. Under Articles 10 and 11, registrants may submit to the Agency information on uses and exposure separately from other registrants of the same substance, whilst they are in principle required to submit jointly information on the intrinsic properties of that substance, subject to the limited exceptions set out in Article 11(3). Consequently, under a compliance check verifying compliance with the information requirements in Annexes VII to X, the Agency is obliged to verify whether a registration dossier includes information on the intrinsic properties of a substance and not to assess the risks posed by that substance. The Agency is not obliged to take into account exposure and risk, unless exceptions are provided for in the REACH Regulation. (Decision of 14.02.2023, Case A-012-2021, Covestro, para. 35-38; Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 201-204).

Chemical safety assessment (Article 14 and Annex I REACH). The objective of Article 14(4) REACH is to ensure a high level of protection of human health and the environment by requiring manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to the substances in question and to develop and recommend appropriate risk management measure, provided that those substances are classified in accordance with the CLP Regulation for at least one of the hazard classes or categories listed in Article 14(4) REACH or are assessed to be PBT or vPvB. (Decision of 28.06.2016, Case A-015-2014, *BASF*, para. 54)

Before classifying a substance pursuant to the CLP Regulation, a registrant must first identify all the hazards posed by the substance based on all information available. (Decision of 28.06.2016, Case A-015-2014, *BASF*, para. 39)

At the hazard identification step and for exposure assessment and risk characterisation, the term 'hazard' does not only mean those effects that lead to classification under the CLP Regulation, which does not address an exhaustive list of endpoints. (Decision of 28.06.2016, Case A-015-2014, *BASF*, para. 39-40, 48 and 56)

Safety data sheet. The SDS needs to include information on all hazards identified and not just those leading to classification pursuant to the CLP Regulation. (Decision of 28.06.2016, Case A-015-2014, *BASF*, para. 42)

Downstream users. Article 37(1) REACH does not place any obligation on downstream users but offers them a possibility to assist in the registration of a substance. Article 37(2) REACH further details this possibility. This is a 'right' and not an obligation. (Decision of 30.05.2017, Case A-022-2015, *Michelin*, para. 80)

Registration of monomers on their own and as components of polymers. Like any other substance, monomers are subject to the general obligation to register. Unreacted monomers that are manufactured in or imported into the EU must be registered under Article 6(1) and (2) REACH inasmuch as they constitute substances on their own. By contrast, polymers are excluded from the registration obligation under Article 2(9) REACH. However, manufacturers and importers of polymers must register the monomer(s) and any other substance(s) contained in their polymers if the conditions set out in Article 6(3) are fulfilled. The REACH Regulation and the case-law of the ECJ therefore establish a distinction between unreacted monomers as substances on their own, which are subject to the registration obligation under Article 6(1) and (2) REACH, and reacted monomers as substances incorporated in polymers after the polymerisation, which are subject to the registration obligation under Article 6(3) REACH. (Decision of 29.06.2021, *SNF*, Case A-001-2020, para. 87-90)

Life-cycle of monomers vs. polymers. Upon polymerisation, a monomer ceases to exist as a substance on its own and is transformed into a new substance, the polymer, which has its own life-cycle. After polymerisation, a monomer is no longer subject to the registration obligation as a substance on its own within the meaning of Article 6(1) and (2) REACH. (Decision of 29.06.2021, SNF, Case A-001-2020, para. 91-92, 100; Decision of 06.06.2018, *SI Group UK and Others*, Case A-006-2016, para. 42)

An importer of a polymer is only subject to the obligation to register the reacted monomers which are incorporated in polymer under Article 6(3) REACH. An importer of a polymer is not subject to the obligation to register under Article 6(1) and (2) REACH the unreacted monomers contained in the imported polymers as residues after polymerisation. (Decision of 29.06.2021, *SNF*, Case A-001-2020, para. 93)

Information on exposure to the monomer after polymerisation (as a residue after polymerisation and/or a degradation product of the polymer) is not part of the standard information requirements to be fulfilled in the chemical safety report of the registered monomer under Article 14(1) REACH. (Decision of 29.06.2021, *SNF*, Case A-001-2020, para. 100)

Relevant time for assessing compliance with test methods. The information submitted by the registrant must comply with the law that is applicable at the time of the submission of that registration dossier. The applicable law includes the test methods. Under Articles 12(2) anI2(1)(c), as soon as the quantity of a substance per manufacturer or importer that has already been registered reaches the next tonnage threshold, the manufacturer or importer must inform the Agency immediately of the additional information it would require under Article 12(1). The updated information must also comply with the law that is applicable at the time of that update. Consequently, to comply with the first subparagraph of Article 13(3), a registrant must respect the version of the relevant test method laid down in the Test Methods Regulation that is applicable at the time it submitted its registration or updated its registration to the tonnage band under which the information requirement in question is required. (Decision of 06.06.2023, Cytec Engineered Materials, Case A-001-2022, para. 40-42, 50)

Presumption of relevance of thyroid effects. Thyroid effects in rats are presumed to be relevant to humans unless it can be shown that they are not. (Decision of 19.09.2023, Case A-009-2022, *Nouryon Functional Chemicals and Others*, para. 112 [currently subject to appeal before the General Court])

11.2. Standard information requirements (Column 1 of Annexes VII-X)

11.2.1. General

Objective. Annexes VII to X REACH require manufacturers and importers of substances to generate and submit to ECHA information on the intrinsic properties of the substances they manufacture or import. This, in turn, contributes to achieving a high level of protection of human health and the environment, which is the main objective of the registration and dossier evaluation provisions in the REACH Regulation. (Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 171-172; Decision of 27.09.2022, Case A-005-2021, *Albemarle Europe,* para. 64-65)

Cumulative requirements. The information requirements set out in Annexes VII to X REACH are cumulative and must therefore be read as a whole. (Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 156; Decision of 27.09.2022, Case A-005-2021, *Albemarle Europe,* para. 42; Decision of 31.10.2022, Case A-011-2021, *Croda EU,* para. 45)

Relevant test methods. Article 13(3) REACH does not limit the scope of test methods to those that have been adopted by OECD as test guidelines. (Decision of 07.12.2016, Case A-013-2014, *BASF*, para. 160)

When novel or unusual test methods are required, it is incumbent on ECHA to work closely with the registrants concerned to maximise the probability of useful results arising from the requested testing (dossier evaluation: Decision of 29.06.2013, Case A-005-2011, *Honeywell Belgium*, para. 200; substance evaluation: Decision of 12.07.2016, Case A-009-2014, *Albemarle Europe*, para. 184)

Studies of limited or unknown reliability (Klimisch 2/4). In order to satisfy directly the information requirements for registration set out in Annexes VII to X, a study must be conducted in accordance with the relevant test method and comply with the requirements of good laboratory practice (if applicable). However, in the context of assessments which involve an examination of all available information – including the assessment of the conditions set out in Column 2 of Section 8.7.3. of Annex IX – a study cannot be simply disregarded if it has shortcomings. In particular, the results of a study of limited or unknown reliability (Klimisch score 2/4) can still be informative, provided that its results and limitations are carefully assessed and that the conclusions drawn from it are adequately weighed and justified. (Decision of 19.09.2023, Case A-009-2022, *Nouryon Functional Chemicals* and Others, para. 117-118 [currently subject to appeal before the General Court])

Flexibility offered by the test method. Where a test method offers flexibility in the study design, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment. (Decision of 25.04.2023, Joined Cases A-002-2022 and A-003-2022, BASF Lampertheim, para. 54)

Route of administration. As regards the appellant's argument that the oral route of administration is not appropriate for testing a respiratory sensitiser and that the request to perform a sub-chronic toxicity study is therefore unjustified, the BoA reiterated that the request for the study was not predicated on a concern regarding respiratory sensitisation, but on the legal obligation to produce information regarding the sub-chronic toxicity of the substance (…). As ECHA had correctly pointed out, whilst the substance was already classified as a respiratory sensitiser it was still necessary to evaluate the systemic toxicity of the substance. (Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 139)

> ***Illustration (EOGRTS)***: From the test method (OECD TG 443/B.56) it is clear that the likely route of human exposure cannot be the only element to take into account in deciding on the route of administration for the conduct of an EOGRTS. Other elements – such as the study design and the known properties of a substance – must also be taken into account. Based on uses of the substances in question as ingredients in cosmetic products for dermal application, humans were likely to be exposed to the substances via the dermal route. However, exposure to the substances may also occur in other ways, for example during the course of the formulation of cosmetic products. In addition, uptake through dermal exposure is normally low. Administering the substances in EOGRT studies using the dermal route would therefore be unlikely to lead to sufficient foetal exposure to give meaningful results. Conducting the EOGRT studies by the oral route, by

contrast, would maximise the likelihood of obtaining useful results from that study. Therefore, ECHA did not commit an error of assessment of breach Section 8.7.3. of Annex IX REACH by requiring the appellant to use the oral route of administration in the EOGRT studies (Decision of 18.08.2020, Case A-009-2018, *Symrise*, para. 170-174; Decision of 18.08.2020, Case A-010-2018, *Symrise*, para. 169-173)

Dose-level setting. Given the difference in exposure duration, it could not be assumed that the effects observed at a certain dose level in the long-term study would appear at the same dose level in an OECD TG 414 study. Consequently, that study did not constitute adequate information for setting the highest dose level in a PNDT study. Moreover, the actual dose intake of the animals in the study is not known with certainty. It may have been considerably higher than 80 mg Mo/kg bw/day. Consequently, that study did not constitute reliable information for setting the highest dose level in a PNDT study. (Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum*, para. 55-58, 60-63, 65-66)

In the context of reproductive toxicity, as in the present case, testing must be performed at appropriately high dose levels in order to provide adequate information on the reproductive toxicity properties of the Substance and to ensure that the data generated are adequate for hazard identification, classification and risk assessment. (Decision of 21.06.2022, Case A-004-2022, *Symrise*, para. 92)

The highest dose level shall aim to induce systemic toxicity, but not death or severe suffering of the animals (paragraph 21 of OECD TG 443). As regards the indication that the dose level selection should be based on fertility effects, the Agency is competent in a compliance check decision under Article 41 to define certain elements of the study design within the flexibility allowed by the applicable test guideline and under the conditions set out in that guideline. OECD TG 443, which sets out the test method for the EOGRTS, provides for flexibility as regards the setting of dose levels. In order to maximise the likelihood of obtaining useful results from the requested study it may be necessary for the Agency to set out requirements for the dose level setting. (Decision of 21.06.2022, Case A-004-2022, *Symrise*, para. 131-133)

Relationship with Article 25. Article 25 requires both the registrants and the Agency to ensure that, in complying with the relevant information requirements, registrants do not carry out unnecessary vertebrate animal testing. If a vertebrate animal study cannot be avoided on the basis of existing information, the –gency is – in accordance with A–ticle 25 – empowered and required to ensure that a vertebrate animal study requested in a compliance check decision is carried out in a way that maximises the likelihood of obtaining useful results and minimises the risk of having to duplicate that study. (Decision of 21.06.2022, Case A-004-2022, *Symrise*, para. 91)

11.2.2. Annexes I and XIII

The Agency required an OECD TG 305 study under Sections 0.6.1. and 4. of Annex I and Section 2.1. of Annex XIII. The BoA held that Annexes I and XIII do not set out information requirements within the meaning of Article 41(3). Consequently, under the compliance check process, the Agency cannot require registrants at the Annex VIII level to submit information to comply with those Annexes. (Decision of 14.02.2023, Case A-012-2021, *Covestro*, para. 119)

11.2.3. Section 2 of Annex VI

Substance identity of nanoforms. Headings 2.1, 2.2 and 2.3 of Section 2 of Annex VI REACH (…) are not information requirements in themselves but headings to describe the subject matter of the points that follow. (…) Equally, the first paragraph of Section 2 of Annex VI REACH, which provides that 'the information given in this section shall be sufficient to enable each substance to be identified', does not constitute an information requirement in itself. It simply states that registrants must provide sufficient information for each of the information requirements listed in Section 2. (Decision of 02.03.2017, Case A-011-2014, *Huntsman P&A UK*, para. 64 and 66)

The wording of Section 2 of Annex VI REACH is clear. It follows that Section 2 of Annex VI REACH cannot be interpreted in the light of its purpose and context so as to include substance

identification information on the crystal phases and/or nanoforms of a substance. (Decision of 02.03.2017, Case A-011-2014, *Huntsman P&A UK*, para. 64 and 69)

Note: Since January 2020, following the amendment of Annex VI REACH by Commission Regulation (EU) 2018/1881 specific information on the nanoforms must be provided in the substance identification under Annex VI REACH.

11.2.4. Column 1 of Section 8.7.2. of Annex IX

Mode of administration (gavage). The REACH Regulation makes no reference to modes of administration. In particular, as regards the oral route of administration, the Annexes do not distinguish between oral administration through the diet and oral administration by gavage. Both test guidelines (PNDT and EOGRTS) allow for flexibility and specific modifications in individual cases on the basis of specific knowledge on e.g. physicochemical or toxicological properties of the test chemical. Such modifications are acceptable when convincing scientific evidence suggests that the modification will lead to a more informative test. When the relevant OECD test guideline provides for flexibility, in a compliance check under Article 41 the Agency may require the registrants to carry out the respective study by using a specific mode of administration, if this mode of administration is possible under the applicable test guideline and necessary to obtain meaningful information on the intrinsic properties of the substance in question. When such a discretion is exercised, whether by the registrant or the Agency, all the necessary information should be taken into account and Article 25 should be adhered to (Decision of 21.06.2023, Case A-004-2022, *Symrise*, para. 47-59, 74)

The 3Rs principle was already taken into account by the European Commission when EU test methods B.31 and B.56, which correspond to the OECD test guidelines 414 and 443, were inserted in the Annex to the Test Methods Regulation. The use of oral administration by gavage is recognised as one of the modes of administration both in the OECD TG 414/EU test method B.31 and the OECD TG 443/EU test method B.56, the legality of which cannot be contested before the Board of Appeal. (Decision of 21.06.2023, Case A-004-2022, *Symrise*, para. 89, 90)

The decision (which requires administration by gavage) does not preclude the Appellant from fulfilling the information requirements set out in the Contested Decision, when in the present case the OECD test guidelines allow for such flexibility and in view of the 3Rs principle, by alternative scientifically justified means (other than the ones requested in the context of the studies required by the Contested Decision). In particular, the Appellant might decide to carry out those studies by having recourse to innovative scientific methods which the Agency could not assess at the time of the adoption of the Contested Decision, provided that the Appellant fills the data-gaps of its registration and takes due account of the objections identified in the Contested Decision as regards the existing studies, the palatability of the Substance and the need to generate adequate data for hazard identification, classification and risk assessment. (Decision of 21.06.2023, Case A-004-2022, *Symrise*, para. 98)

11.2.5. Column 1 of Section 8.7.3. of Annex IX

General. An EOGRTS with the basic study design is a standard information requirement for registration under Column 1 of Section 8.7.3. of Annex IX if the available information shows at least one of the following: (1) adverse effects on reproductive organs, (2) adverse effects on reproductive tissues, or (3) other concerns in relation to reproductive toxicity. (Decision of 19.09.2023, Case A-009-2022, *Nouryon Functional Chemicals* and Others, para. 35 [currently subject to appeal before the General Court])

According to the sixth introductory paragraph to Annex IX, the choices made in relation to the study design of the EOGRTS must ensure that the data generated through that study are adequate for hazard identification and risk assessment. The same objective is set out in Recital 7 of Commission Regulation (EU) 2015/28211 and paragraph 22 of OECD TG 443. (Decision of 29.08.2023, Case A-006-2022, *Symrise and Others*, para. 39)

Route of administration. It is clear from Article 13(3) read in conjunction with Column 1 of Section 8.7.3. of Annex IX that the method to be followed to carry out the EOGRTS is set out in OECD TG 443, to which the Contested Decision refers.14 OECD TG 443 recognises both oral

administration by gavage and through the diet as ways to administer the substance to be tested.15 By not imposing any specific mode of administration, the Contested Decision gives the Appellants the discretion to decide whether to carry out the EOGRTS via oral administration through the diet. (Decision of 29.08.2023, Case A-006-2022, *Symrise and Others*, para. 44)

Mode of administration (gavage). (See under Column 1 of Section 8.7.2. of Annex IX)

Preliminary investigation of gut microbiome. Column 1 of Section 8.7.3. of Annex IX makes no reference to studies aimed at investigating the effects of a substance on the gut microbiome. That provision only mentions repeated dose toxicity studies (for example 28-day or 90-day studies, OECD TG 421 or OECD TG 422 screening studies) as the source of information on concerns which may justify the need to carry out an EOGRTS. It is clear from that provision that the investigation of the effects of the Substance on the gut microbiome is not a standard information requirement for registration purposes. Furthermore, as confirmed by the Appellants at the hearing, the investigation of the effects of the Substance on the gut microbiome is not a preliminary doserange finding study aimed at determining the appropriate dose for the main study. That investigation is rather a specific study for the Substance seeking to establish the concentration at which the gut microbiome activity is inhibited. (Decision of 29.08.2023, Case A-006-2022, *Symrise and Others*, para. 35-36)

Dose-levels. The Agency committed no error in requiring in the Contested Decision that the highest dose level must be set on the basis of clear evidence of an adverse effect on sexual function and fertility. (Decision of 29.08.2023, Case A-006-2022, *Symrise and Others*, para. 59-70).

Dose-dependency of observed effects. It is not necessary for the Agency to establish the dose-dependency of observed effects in order to find that one or more of the conditions set out in Column 1 of Section 8.7.3. of Annex IX are met. Whether the substance actually causes reproductive toxicity effects and whether those effects are dose-dependent is to be examined through the conduct of the EOGRTS. Under Column 1 of Section 8.7.3. of Annex IX, such an assessment would be premature. (Decision of 19.09.2023, Case A-009-2022, *Nouryon Functional Chemicals and Others*, para. 64 [currently subject to appeal before the General Court])

11.2.6. Column 1 of Section 9.2. of Annex IX

Requirement. The information on degradation under Column 1 of Section 9.2. of Annex IX must be submitted unless the registrant submits an acceptable specific adaptation under Column 2 of the corresponding provision or an acceptable general adaptation under Annex XI. (Decision of 14.02.2023, Case A-012-2021, *Covestro*, para. 56; Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 249-251)

Information on non-extractable residues (NER). the provision of information on NERs is a requirement of both soil simulation testing and sediment simulation testing under the Test Methods Regulation. Registrants must carry out the tests in full compliance with those test methods. (Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 277)

However, the provision of information on NERS is not a requirement of simulation testing on ultimate degradation in surface water according to Section C.25. of the Annex to the Test Methods Regulation. (Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 284-285)

11.2.7. Column 1 of Section 8.7.2. of Annex X

PNDT study in a second species. The information requirements set out in Column 1 of Annexes VII-X REACH are cumulative and, under sec. 8.7.2 of Annex X REACH, registrants can be required to perform a pre-natal developmental toxicity study on a species other than the species used for a pre-natal developmental toxicity study under Column 1 of sec. 8.7.2 of Annex IX REACH (unless exceptions apply). (Decision of 10.10.2013, Case A-004-2012, *Lanxess Deutschland*, para. 72-73 and 86; Decision of 29.04.2021, Case A-014-2019, *LG Chem Europe*, para. 32, 34, 38; Decision of 31.10.2022, Case A-011-2021, *Croda EU*, para. 23)

11.3. Adaptations from standard information requirements (Column 2 of Annexes VII-X, Annex XI)

11.3.1. General

General. A registrant is entitled to adapt the standard information requirements set out in Annexes VII to X REACH (the 'testing Annexes'), either under the specific adaptation rules in Column 2 of those Annexes, if applicable, or under the general adaptation rules in Annex XI REACH. This possibility is set out in the introductory paragraphs of each of the testing Annexes. (Decision of 29.06.2021, SNF, Case A-001-2020, para. 57)

In principle, Column 2 of each annex applies only to Column 1 of that same annex. (Decision of 29.04.2021, Case A-014-2019, *LG Chem Europe*, para. 36; Decision of 31.10.2022, Case A-011-2021, *Croda EU*, para. 46)

> ***Illustration.*** An appellant argued that Column 2 of Section 8.7.2. of Annex IX also applies to Annex X and, therefore, also at Annex X level a PNDT study in a second species is required only if there are indications that a substance has adverse developmental effects. The BoA found that, considering its wording, context and objectives, Column 2 of Section 8.7.2. of Annex IX applies only under Annex IX, and not under Annex X. (Decision of 31.10.2022, Case A-011-2021, *Croda EU*, para. 38-56, 77-83)

The possibility to have recourse to adaptations is not limited to the initial stage of the dossier evaluation procedure but also applies to subsequent stages of that procedure. (Decision of 29.06.2021, SNF, Case A-001-2020, para. 59)

Requirements. A registrant who submits an adaptation must set out clearly, in the relevant part of its registration dossier, the provision of Annexes VII to XI REACH on which the adaptation is based, the grounds for the adaptation, and the scientific information which substantiates those grounds. (Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 35; Decision of 01.08.2016, Case A-014-2014, *BASF Pigment*, para. 47; Decision of 31.10.2022, Case A-011-2021, *Croda EU*, para. 79; Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 59)

The registrant must clearly set out the reasons for his decision not to provide certain information, so as to allow ECHA to assess the applicability of the relevant exception. ECHA is not required to compile adaptation arguments on behalf of the registrant from the information set out in other parts of the registration dossier. (Decision of 10.10.2013, Case A-004-2012, *Lanxess Deutschland*, para. 92-93, 98-99; Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 57-60; Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 59)

Arguments on appeal beyond adaptations in dossier. In full compliance with the duty to state reasons, it is necessary for the BoA to respond to arguments setting forth new adaptations by examining whether the information submitted by the Appellant prior to the adoption of the Contested Decision would comply with that adaptation. (Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 122)

Role of ECHA. It is not incumbent upon ECHA to develop or improve adaptations on the registrant's behalf. (Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 37; Decision of 09.02.2021, Case A-015-2019, *Polynt*, para. 85; Decision of 01.08.2016, Case A-014-2014, *BASF Pigment*, para. 47-48, 55 and 68; Decision 01.08.2016, Case A-003-2015, *BASF Pigment*, para. 53-55, 62 and 74; Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 59)

While registrants can expect a certain level of expertise within ECHA, it is not the task of ECHA to develop, or improve, read-across adaptations on their behalf. (Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 98; Decision of 19.06.2013, Case A-001-2012, *Dow Benelux*, para. 116; Decision of 07.10.2016, Case A-017-2014, *BASF*, para. 62;

Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 123; Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 86; Case A-006-2018, *Emerald Kalama Chemical and Others*, para. 61; Decision of 23.02.2021, Joined Cases A-016-2019 to A-029-2019, *Lubrizol France and Others*, para. 76 and 124)

It is the sole responsibility of registrants to generate, gather and submit to ECHA information that will substantiate an adaptation in accordance with the requirements of the REACH Regulation. Article 40 does not empower ECHA to require registrants to generate, gather and submit information to substantiate an adaptation. (Decision of 29.04.2021, Case A-014-2019, *LG Chem Europe*, para. 59; Decision of 23.02.2021, Joined Cases A-016-2019 to A-029-2019, *Lubrizol France and Others,* para. 76, 115, 126)

ECHA is not required to assess, and state reasons for rejecting, adaptations which are not contained in the registration dossier under evaluation. (Decision of 31.10.2022, Case A-011-2021, *Croda EU*, para. 82-83)

Article 77(2)(j) REACH tasks ECHA with '*providing advice and assistance to manufacturers and importers registering a substance in accordance with Article 12(1)*'. As is apparent from its wording, that provision concerns technical assistance for the submission of registration dossiers. Article 77(2)(j) REACH does not impose on ECHA any obligations as regards the development of a testing proposal or adaptation and helping a registrant in their preparation. (Decision of 23.02.2021, Joined Cases A-016-2019 to A-029-2019, *Lubrizol France and Others,* para. 77)

Strict interpretation of waiving provisions. Column 2 to each of Annexes VII to X REACH contains a series of specific adaptation rules that apply to the standard information requirements. Some of those specific adaptation rules allow for the standard information required in the Column 1 to be omitted if the conditions set out in Column 2 are fulfilled. As they constitute an exception from the legal obligation to provide standard information, these rules must be interpreted restrictively as regards the conditions under which the standard information referred to in Column 1 could be omitted. (Decision of 09.02.2021, Case A-015-2019, *Polynt*, para. 40)

No general requirement to wait for the improvement of an adaptation. Without prejudice to specific provisions of the REACH Regulation and the requirements of principle of good administration, ECHA does not have a legal obligation to wait for registrants to improve their justification for an adaptation. (Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 49; Decision of 09.02.2021, Case A-015-2019, *Polynt*, para. 85; Decision of 29.04.2021, Case A-014-2019, *LG Chem Europe*, para. 56)

The provision of information in a registration dossier should not be (further) delayed by events which are outside the control of the registrant, such as the completion of a study by a third party which is not subject to obligations towards the registrant. (Decision of 10.10.2013, Case A-004-2012, *Lanxess Deutschland*, para. 50-60)

11.3.2. Column 2 of Section 9.2. of Annex VIII

Justification for further degradation studies. Under that provision, a registrant must consider whether further degradation testing is needed to investigate further the degradation of the substance in question. If that registrant concludes, based on its consideration of the CSA, that such further degradation testing is not required, it must clearly set out in its registration dossier the reasons for that conclusion. This is essential to allow the Agency to assess the validity of the registrant's decision not to perform further degradation testing under Column 2 of Section 9.2. of Annex VIII (Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 236)

Column 2 of Section 9.2. of Annex VIII is not an exception to the principle that, under a compliance check verifying compliance with the information requirements in Annexes VII to X, the Agency is not obliged to take into account information on exposure and risk related to a

substance. The Agency is not under the obligation to assess exposure and risk for the purposes of requesting additional information on degradation under Column 2 of Section 9.2. of Annex VIII. (Decision of 14.02.2023, Case A-012-2021, Covestro, para. 40, 47)

A decision, based on the available information, that a Iubstance is a potential PBT or vPvB can justify a request for additional information on degradation under Column 2 of Section 9.2. of Annex VIII (Decision of 14.02.2023, Case A-012-2021, Covestro, para. 52; Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 240)

In certain cases, the standard information on degradation under Column 1 of Annexes VII, VIII and IX may be insufficient to allow for conclusions to be reached on the degradation of a substance. Consequently, it may be necessary, in certain circumstances, to require additional information on degradation. Column 2 of Section 9.2. of Annex VIII allows for further information on the degradation of a substance to be obtained. Column 2 of Section 9.2. of Annex IX allows for further information on degradation to be obtained, not only on the substance, but also on the degradation products of that substance. In comparison with the requirements under Column 1 of Sections 9.2. of Annexes VII to IX, Column 2 of Annexes VIII and IX go beyond the standard information requirements. Such further testing is required if the CSA indicates the need to investigate further. For substances registered in quantities of 10 tonnes or more per year, a CSA according to Article 14 must be carried out. The CSA includes an assessment of a human health, environmental and physico-chemical hazard, and PBT and vPvB assessments. If the substance fulfils the criteria for any of the hazard classes listed in Article 14(4), the CSA also includes an exposure assessment and risk characterisation. This means that the content of a CSA depends on whether the existing information indicates a need for further information to be included in the CSA. In other words, the content of the CSA, and therefore the potential need for further testing under Column 2, is substance-specific. (Decision of 27.09.2022, *Albemarle Europe*, A-005-2021, para. 50 ff., 89 ff.)

Meaning of 'consider'. The Appellant's argument that the obligation 'to consider' in Column 2 of Section 9.2. of Annex VIII is less stringent than the obligation 'to propose' which appears, for example, in Column 2 of Section 9.2. of Annex IX must be rejected. Under both requirements there is an obligation for registrants to examine the available information, and if the requirements of the provision in question are met, there is an obligation to provide the information required by that provision. The use of the verb 'consider' in the version of Column 2 of Section 9.2. of Annex VIII that was applicable at the time of the adoption of the Contested Decision, i.e. on 26 August 2021, cannot be interpreted as authorising a registrant not to take any action and not provide the necessary information if the CSA indicates the need to investigate further the degradation of the substance at issue. (Decision of 14.02.2023, Case A-012-2021, Covestro, para. 57)

Identification of degradation products. Column 2 of Section 9.2. of Annex VIII refers to the need to investigate further the degradation of a substance, which includes the process of degradation and the identification of the degradation products of that substance. Degradation testing includes the identification of degradation products. The difference in wording between Column 2 of Section 9.2. of Annexes VIII and IX does not mean that information on the identification of degradation products cannot be requested at the Annex VIII level. Column 2 of Section 9.2. of Annex VIII allows for further information on the degradation of a substance to be obtained, and therefore may include information on the identification of degradation products. (Decision of 14.02.2023, Case A-012-2021, Covestro, para. 101-105; Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022 para. 232 ; Decision of 27.09.2022, *Albemarle Europe*, A-005-2021, para. 50 ff., 89 ff.)

11.3.3. Column 2 of Section 8.7.2. of Annexes IX, X

Difference to Section 1.2. of Annex XI. Column 2 (PNDT) of Annexes IX, X and WoE adaptations serve different purposes. Column 2 (PNDT) means that information on the PNDT endpoint is not needed whilst a WoE adaptation means that the information on the PNDT endpoint already exists. The evidence to justify one adaptation is therefore unlikely to support the other. (Decision of 01.08.2016, Case A-014-2014, *BASF Pigment*, para. 30; Decision 01.08.2016, Case A-003-2015, *BASF Pigment*, para. 31)

Closed list of conditions. The Column 2 adaptation contains a closed list of conditions which, if fulfilled, relieve registrants of the obligation to conduct studies on reproductive toxicity. (Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 87; Decision of 09.02.2021, Case A-015-2019, *Polynt*, para. 41)

Column 2 (PNDT) adaptation includes three cumulative conditions: (1) low toxicological activity, (2) no systematic absorption via relevant routes of exposure based on toxicokinetic data and (3) no or no significant human exposure. (Decision of 01.08.2016, Case A-014-2014, *BASF Pigment*, para. 32-38; Decision of 01.08.2016, Case A-003-2015, *BASF Pigment*, para. 40)

Evidence of low bioavailability does not satisfy the 'no absorption' condition. If a surrogate to the 'no absorption' condition, or the possibility to substitute test results showing no absorption by results of low absorption, were possible the legislator would have reflected this in the wording of the Column 2 adaptation. Furthermore, the criterion is no absorption rather than low absorption. As a consequence, showing that one remains below the cut-off criteria for the classification of mixtures under the CLP Regulation is irrelevant. (Decision of 01.08.2016, Case A-003-2015, *BASF Pigment*, para. 40 and 42)

No waiving based on SVHC identification and stringent risk management measures (as a respiratory sensitiser). The Column 2 adaptation does not make provision for waiving the requirement to conduct studies on reproductive toxicity on the basis that a substance has been identified as a substance of very high concern ('SVHC') due to its respiratory sensitising properties. It is clear from the Column 2 adaptation, red in light of Recital 19, that the fact that stringent risk management measures were in place to protected users from the sensitisation hazard did not affect the appellant's obligation to provide information on other endpoints, assess all the risks related to the substance and develop appropriate risk management measures with regard to all those risks, and not only to respiratory sensitisation. In the absence of standard information on all endpoints there was uncertainty as to whether the respiratory sensitisation potential of the substance poses the greatest risk. Data derived from a PNDT study could, in principle, lead to or affect authorisation and restrictions decisions regarding the substance or lead to different risk management measures being required. (Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 88-94)

Requirement for a PNDT study in a second species under Annex IX. If a registrant considers that a second species PNDT study is not required under Annex IX REACH, pursuant to the adaptation possibility at Column 2 of Section 8.7.2. of Annex IX REACH it must include a justification to that effect in its registration dossier. (Decision of 10.10.2013, Case A-004-2012, *Lanxess Deutschland*, para. 79; Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 109-110)

Under Column 1 of Section 8.7.2. of Annex X, a PNDT study in a second species is a standard information requirement for registrants at the tonnage band of 1 000 tonnes or more per year. Under Column 2 of Section 8.7.2. of Annex IX, that same study is an additional requirement for registrants at the tonnage band of 100 to 1 000 tonnes per year if an assessment of the outcome of the PNDT study in a first species and all other relevant available data show that this is necessary. Column 2 of Section 8.7.2. of Annex IX is therefore not a '*waiver*' for the requirement to conduct a PNDT study in a second species under any annex, but a requirement or '*trigger*' to conduct that study already under Annex IX if available information shows that this is necessary. (Decision of 31.10.2022, Case A-011-2021, *Croda EU*, para. 47)

The wording 'or the next' does not stand alone. It must be read together with the rest of Column 2 of Section 8.7.2. of Annex IX. That provision refers to '[a] decision on the need to perform a study at this tonnage level or the next on a second species […]'. The decision referred to in

Column 2 of Section 8.7.2. of Annex IX is a decision as to whether a PNDT study in a second species should be performed at the Annex IX level or at the next. It is not a decision, as the Appellant argues, as to whether a PNDT on a second species should be performed at both the Annex IX and X levels, or not at all. If the outcome of the study in a first species and all other relevant available data show a need to perform a study in a second species 'at this level' (Annex IX), then the PNDT study in a second species must be performed under Annex IX. If the outcome of the study in a first species and all other relevant available data do not show a need to perform a study in a second species, then the PNDT study in a second species must be performed 'only at the next [level]' (Annex X). (Decision of 31.10.2022, Case A-011-2021, *Croda EU*, para. 48)

11.3.4. Column 2 of Section 8.7.3. of Annex IX (EOGRTS extensions)

Inclusion of cohorts 2A/2B and 3. The second paragraph of Section 8.7.3. of Annex IX must be interpreted as meaning that registrants who are required to submit information on an EOGRTS as standard information are also required to include cohorts 2A and 2B in the EOGRTS if the available information gives reasonable grounds for considering that a substance may cause effects related to (developmental) neurotoxicity, and cohort 3 if the available information gives reasonable grounds for considering that a substance may cause effects related to (developmental) immunotoxicity. (Decision of 19.09.2022, Case A-009-2022, *Nouryon Functional Chemicals and Others*, para. 77 [decision currently subject to appeal before the General Court])

The second paragraph of Column 2 of Section 8.7.3. of Annex IX does not state that the (developmental) neurotoxicity effects observed in the available studies must be especially serious or severe. On the contrary, it is sufficient that the available information gives reasonable grounds for considering that a substance may cause (developmental) neurotoxicity effects. ((Decision of 19.09.2022, Case A-009-2022, *Nouryon Functional Chemicals and Others*, para. 107 [decision currently subject to appeal before the General Court])

If one or more of those conditions are fulfilled, the Agency has no discretion as to the measure to be taken (Decision of 19.09.2022, Case A-009-2022, *Nouryon Functional Chemicals and Others*, para. 78 [decision currently subject to appeal before the General Court])

The second paragraph of Column 2 of Section 8.7.3. of Annex IX refers to 'relevant changes in thyroidal hormone levels associated to adverse effects' merely as one example of a concern based on specific mechanisms/modes of action with an association to (developmental) neurotoxicity. There is no obligation for the Agency to base its assessment exclusively on existing hormone level measurements. On the contrary, it is sufficient that the available information gives reasonable grounds to consider that a substance might have (developmental) neurotoxicity effects. (Decision of 19.09.2022, Case A-009-2022, *Nouryon Functional Chemicals and Others*, para. 102 [decision currently subject to appeal before the General Court])

Additional investigations of learning and memory function. Investigations on learning and memory function are not an information requirement for the Appellants' registration of the Substance under the second paragraph of Column 2 of Section 8.7.3. of Annex IX in conjunction with Article 13(3) and paragraph 50 of EU test method B.56. (Decision of 25.04.2023, Joined Cases A-002-2022 and A-003-2022, BASF Lampertheim, para. 62; Decision of 19.09.2022, Case A-009-2022, *Nouryon Functional Chemicals and Others*, para. 137 [decision currently subject to appeal before the General Court])

11.3.5. Column 2 of Section 9.1. of Annex IX REACH (aquatic toxicity)

Column 2 of Section 9.1. of Annex IX REACH is neither a 'trigger', nor a 'waiver' for the requirement to submit information on one of the three long-term toxicity tests on fish under Column 1 of Section 9.1.6. of Annex IX REACH. Instead, Column 2 of Section 9.1. of Annex IX REACH requires registrants to submit at least the standard information set out in Column 1 of Section 9.1.6 REACH. The registrants may be required to submit information on a further study than one of the three listed in Column 1 of Section 9.1.6. of Annex IX REACH, if the chemical safety assessment indicates that it is necessary to investigate the effects of a substance on

aquatic organisms beyond what any one of those three studies would do. (Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 154-175; Decision of 18.08.2020, Case A-010-2018, *Symrise*, para. 186-187; Decision of 19.01.2021, Case A-010-2019, *Croda Iberica SA*, para. 37; Decision of 07.09.2021, Case A-008-2020, *Sustainability Support Services (Europe)*, para. 58)

11.3.6. Column 2 of Section 9.2. of Annex IX REACH (degradation)

Based on its wording, context and objectives, Column 2 of Section 9.2. of Annex IX must be interpreted as meaning that a registrant at the Annex IX level proposes biotic degradation testing which is further to that already required under Column 1 of Section 9.2. of Annex IX 'if the CSA for the substance indicates the need to investigate further the degradation of the substance and its degradation products'. 68. Therefore, the Agency did not act ultra vires in requesting in the Contested Decision standard information on the identification of degradation products on the basis of Column 1 of Section 9.2.3. of Annex IX. (Decision of 27.09.2022, *Albemarle Europe*, A-005-2021, para. 67-68)

Column 2 of Section 9.2. of Annex IX is'neither'a '*trig*'*er*' nor a '*waiver*' for the requirement to submit information under Column 1 of Section 9.2. of Annex IX. The information requirements under Column 1 of Section 9.2. of Annex IX are standard information requirements which oblige registrants to provide, and allow the Agency to require, information on the degradation of the substance at issue. Under Column 2 of Section 9.2. of Annex IX the registrant may be required to submit information on biotic degradation which is further or additional to the standard information requirements under Column 1 of Section 9.2. of Annex IX. (Decision of 27.09.2022, Case A-005-2021, *Albemarle Europe*, para. 62-63)

Column 2 of Section 9.2. of Annex IX allows for further information on degradation to be obtained, not only on the substance, but also on the degradation products of that substance. Decision of 14.02.2023, Case A-012-2021, Covestro, para. 106)

11.3.7. Column 2 of Section 9.2.3. of Annex IX REACH (degradation products)

The information requirement under Section 9.2.3. of Annex IX on the identification of degradation products is dependent on the information requirements under Column 1 of Section 9.2.1. of Annex IX and the degradation study under Section 9.2.2.1. of Annex VIII. To comply with Column 1 of Section 9.2.3. of Annex IX, a registrant must provide either (i) information on the identification of the degradation products resulting from the standard information requirements on degradation set out in Column 1 of Section 9.2.1. of Annex IX and in Column 1 of Section 9.2.2.1. of Annex VIII, or (ii) an acceptable specific adaptation under Column 2 of the corresponding provisions or an acceptable general adaptation under Annex XI. (Decision of 27.09.2022, Case A-005-2021, *Albemarle Europe*, para. 96-102)

> ***Illustration:*** ECHA misinterpreted and misapplied Column 1 of Section 9.2.3. of Annex IX as it required the identification of degradation products without examining first the adaptations by which the appellant had omitted the information requirements under Section 9.2.1. of Annex IX and Section 9.2.2.1. of Annex VIII. (Decision of 27.09.2022, Case A-005-2021, *Albemarle Europe,* para. 103-106)

11.3.8. Section 1.1. of Annex XI REACH (Use of existing data)

General. A registrant seeking to fulfil a standard information requirement by other data under Section 1.1.2. of Annex XI REACH must establish that the data provided contains adequate and reliable coverage of the key parameters that would be investigated in a study performed in accordance with the relevant test method referred to in Article 13(3) REACH. (Decision of 29.06.2021, SNF, Case A-001-2020, para. 41-42)

11.3.9. Section 1.2. of Annex XI REACH (Weight of evidence)

General. In order for a WoE adaptation to succeed, the focus has to be meeting the information requirements for the respective endpoint, e.g. the key parameters need to be covered. (Decision of 01.08.2016, Case A-014-2014, *BASF Pigment*, para. 49; Decision 01.08.2016, Case A-003-2015, *BASF Pigment*, para. 56)

The requirements for a general adaptation under Section 1.2. of Annex XI REACH must be read in conjunction with the specific information requirement in the testing Annexes which the adaptation seeks to fulfil. (Decision of 21.10.2020, Case A-001-2019, *Solvay Fluor*, para. 140; Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 39; Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 70-71)

> ***In particular: EOGRTS.*** In order to successfully rely on an adaptation under Section 1.2. of Annex XI REACH to fill Section 8.7.2. of Annex IX REACH, a registrant must demonstrate that the available information adequately identifies and characterises the pre-natal developmental toxicity of the substance at issue. In order to adequately identify and characterise the pre-natal developmental toxicity of a substance there must be a sufficiently long duration of exposure to that substance in the studies relied on by the registrant. (Decision of 21.10.2020, Case A-001-2019, *Solvay Fluor*, para. 140-141; Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 39-41, 85-87)
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> ***In particular: 90-day study***. The requirements for a general adaptation under Section 1.2. of Annex XI REACH must be read in conjunction with the specific information requirement in Annexes VII to X which the adaptation seeks to fulfil. Section 8.6.2. of Annex IX REACH requires registrants to submit information that allows the identification and characterisation of the toxicity of a substance resulting from a sub-chronic (90-day) exposure. Therefore, in order to apply an adaptation under Section 1.2. of Annex XI to Section 8.6.2. of Annex IX REACH, a registrant must demonstrate that available information is sufficient to identify and characterise the toxicity of a substance resulting from a sub-chronic (90-day) exposure. (Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 39-41, 76-78)
>
> ***In particular: In vitro gene mutation in bacteria***. Section 8.4.1. of Annex VII requires registrants to submit information on in vitro gene mutation in bacteria. In order to successfully rely on an adaptation under Section 1.2. of Annex XI to fulfil that information requirement, a registrant must demonstrate that the available information is sufficient for that purpose. (Decision of 06.06.2023, *Cytec Engineered Materials*, Case A-001-2022, para. 71)

Using WoE to meet column 2 adaptation. A WoE adaptation can be used to show that all the conditions of a column 2 adaptation are met. (Decision of 01.08.2016, Case A-014-2014, *BASF Pigment*, para. 43; Decision 01.08.2016, Case A-003-2015, *BASF Pigment*, para. 50)

QSAR model applicability domain. In the case of the VEGA model, the values are not reliable because most of the transformation and/or degradation products are, or may be, outside the applicability domain of the model. This means that the predicted transformation and/or degradation products are not substances for which these QSAR models are considered to gibe reliable results. (Decision of 15.01.2019, Case A-004-2017, *3v Sigma*, para. 68)

11.3.10. Section 1.5. of Annex XI REACH (read-across)

General. Section 1.5. of Annex XI REACH allows for an adaptation if it is established that (i) the substances in a group or category are structurally similar, (ii) the properties of the substances are likely to be similar or follow a regular pattern, and (iii) the similarity of properties or their regular pattern is the result of structural similarity. (Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 66; Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 87; Decision of 23.02.2021, Joined Cases A-016-2019 to A-029-2019, *Lubrizol France and Others,* para. 66 and 100; Decision of 09.11.2021, Case A-009-2020, *Polynt* [currently subject to appeal before the General Court], para. 127; Decision of 23.08.2022, Case A-004-2021, *Celanese Production Germany*, para. 36)

Structural similarity. The required level of information on substance identification must be determined on a case-by-case basis. It is not necessary in every case to have all data required under REACH (Annex VI), but, in some cases (e.g., UVCB), additional or different information may be required. (Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 70-71)

Similar properties/regular pattern. Read-across adaptations are endpoint-specific; registrants and ECHA should take into account any other information, such as other endpoints, which may be relevant to a read-across adaptation. (Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 83)

In order to rely on an adaptation under Section 1.5. of Annex XI, it is not necessary for a registrant to show that the intrinsic properties of two substances are identical. It is sufficient to show that the properties are likely to be similar or follow a regular pattern (Decision of 23.08.2022, Case A-004-2021, *Celanese Production Germany*, para. 40 and 44-49)

Breakdown products. The similarities under Section 1.5. of Annex XI may be based on likelihood of common breakdown products (Decision of 23.08.2022, Case A-004-2021, *Celanese Production Germany*, para. 38)

Adequate and reliable documentation. Registrants should explain the premise for a read-across adaptation proposed, for example, by creating an implicit or explicit hypothesis, and then show that the evidence supports that premise within the legal requirements of the REACH Regulation. It is then ECHA's task to examine whether registrants have satisfactorily achieved this. In doing so, it needs to balance the objectives of the read-across provisions with the inherent uncertainty in any read-across adaptation and the need for predictive (eco)toxicology to be alert to the unexpected. (Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 60 and 62; Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 86)

When relying on a read-across adaptation to satisfy registration requirements, registrants are responsible for establishing that the adaptation complies with the conditions set out in Section 1.5. of Annex XI REACH. The task of ECHA is to examine whether the evidence provided by the registrant demonstrates that a read-across adaptation meets the requirements set out in Section 1.5. of Annex XI. (Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 86; Decision of 24.03.2020, Case A-006-2018, *Emerald Kalama Chemical and Others*, para. 61-62; Decision of 09.11.2021, Case A-009-2020, *Polynt* [currently subject to appeal before the General Court], para. 126)

Even if structural similarity and similarity of properties are demonstrated this is not necessarily sufficient, on its own, to justify read-across adaptation, if the premise for adaptation is not set out with sufficient clarity. (Decision of 13.02.2014, Case A-006-2012, *Momentive Specialty Chemicals*, para. 67)

Unexplained differences between source and target substances. Given the unexplained differences between the no observed adverse effect-levels ('NOAELs') for the grouped substances, and the unexplained differences in renal effects between those substances, the appellant had not adequately justified the premise that the structural differences between the grouped substances do not cause different toxicological effects. (Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 124-137)

Parallel procedures. The ECHA decisions requesting testing on the substance and on the source substance were not inconsistent. In both cases the registrant was requested to perform testing on the substance which is the subject of the decision. Whilst the appellant intended to perform testing on only one substance, it was not possible for a read-across adaptation to be accepted as the appellant had not demonstrated that the '*toxicological […] properties are likely to be similar or follow a regular pattern*' (Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 146)

***QSAR as support for read-across*.** Care must be taken when applying one predictive tool (QSAR) to justify the use of another predictive tool (read-across). The QSAR model included in

the registration update helped to support the read-across adaptation proposed by the appellant. However, it was not sufficient to demonstrate that the read-across proposed actually works in practice. The problem of the lack of test data on the properties of the two substances could not be overcome by reference to a QSAR model alone. (Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 96)

Read-across adaptation for UVCB substances. Nothing in Section 1.5. of Annex XI REACH ('Grouping of substances and read-across approach') or elsewhere in the REACH Regulation precludes the use of read-across adaptations for UVCB substances. (Decision of 29.04.2021, Case A-014-2019, *LG Chem Europe*, para. 62)

11.3.11. Section 3. of Annex XI REACH (exposure-based waivers)

General. Section 3 of Annex XI REACH sets out the rules for an exposure-based adaptation that can be applied to any registered substance with a view to omitting testing in accordance with Sections 8.6. and 8.7. of Annex VIII REACH and in accordance with Annexes IX and X REACH. A registrant seeking to rely on an exposure-based adaptation must provide adequate justification and documentation. The justification must be based on a thorough and rigorous exposure assessment that must meet one of the criteria defined in point 3.2. of Section 3 of Annex XI REACH. (Decision of 29.06.2021, *SNF*, Case A-001-2020, para. 97)

Substance used as an ingredient in cosmetic products. Section 3 of Annex XI REACH in conjunction with Article 14(5)(b) REACH allows registrants to forgo testing on a substance used as an ingredient in cosmetic products from carrying out studies if they establish that there is no, or only negligible, exposure from other sources than the finished cosmetic product. The other conditions of Section 3 of Annex XI REACH must also be met. (Decision of 18.08.2020, Case A-009-2018, *Symrise*, para. 91-92; Decision of 18.08.2020, Case A-010-2018, *Symrise*, para. 92-93)

Monomers and polymers. Where a monomer is registered pursuant to Article 6(3) REACH, information on the presence of a monomer in polymers as a residue after polymerisation and/or as a degradation product of the polymer is not standard information required for the purposes of a registration under Article 14(1) REACH. However, if the registrant wishes to rely on an exposure-based waiver under Section 3 of Annex XI REACH, it must also establish that there is no, or no significant, exposure to the monomer as a residue after polymerisation and/or as a degradation product of the polymer. The exposure assessment to be submitted under Section 3 of Annex XI REACH might oblige the importer of a polymer to provide information on the exposure to the monomer after polymerisation. (Decision of 29.06.2021, *SNF*, Case A-001-2020, para. 101-109)

11.4. PBT assessment (Annex XIII REACH)

Difference to WoE adaptations under Section 1.2. of Annex XI REACH. As regards the appellant's allegation that ECHA failed to take into account its '*weight of evidence argument*' that the substance does not affect male reproduction, the BoA recalled that ECHA is not obliged to adopt a weight-of-evidence approach to reach a conclusion regarding a particular property in the context of substance evaluation, the question being rather whether ECHA failed to take relevant information into account. (Decision of 19.12.2016, Case A-018-2014, *BASF*, para. 202)

Data obtained under relevant conditions. Annex XIII REACH refers to '*relevant conditions*' and not '*real life conditions*'. There is also nothing in Annex XIII REACH to suggest that testing conditions for bioaccumulation must be limited to the most frequent patterns of distribution of a substance in the environment. In light of the above, the BoA finds that '*relevant conditions*' within the meaning of Annex XIII REACH means those conditions that allow for an objective assessment of the PBT/vPvB properties of a substance and not the PBT/vPvB properties of a substance in particular environmental conditions. (Decision of 07.12.2016, Case A-013-2014, *BASF*, para. 112-114; Decision of 15.01.2019, Case A-004-2017, *3v Sigma*, para. 57; Decision of 19.12.2016, Case A-018-2014, *BASF*, para. 47-48)

There is nothing in Section 1.1.1 of Annex XIII REACH to suggest that the '*relevant conditions*' for the assessment of persistence must be limited to the most frequent patterns of distribution of a substance in the environment. Section 1.1.1 of Annex XIII REACH requires that information generated in '*any'* of the above compartments can be used to assess the persistence of a substance. This does not preclude testing for persistence in multiple compartments if it is necessary to do so. (Decision of 19.12.2016, Case A-018-2014, *BASF*, para. 49)

It is apparent from the use of the word '*any*' in Section 1.1.1. of Annex XIII REACH that a substance can be found to be persistent in the environment if its half-life in any one of the five listed environmental compartments exceeds the relevant threshold. Bearing in mind that the purpose of persistence testing pursuant to substance evaluation is to clarify an intrinsic property of a substance, and not the persistence of a substance in particular environmental conditions, it follows that '*relevant conditions*' within the meaning of Annex XIII REACH means those conditions that allow for an objective assessment of the persistence of a substance, specifically against the half-life criteria set out in Section 1.1.1. of Annex XIII REACH. (Decision of 19.12.2016, Case A-018-2014, *BASF*, para. 87)

The known physico-chemical properties of a substance must be taken into account when assessing the '*relevant conditions*' which apply. (Decision of 07.12.2016, Case A-013-2014, *BASF*, para. 112-114)

Bioaccumulation. Under Section 12(3) of Annex II REACH, bioaccumulation potential means the '*potential of a substance […] to accumulate in biota and, eventually to pass through the food chain*'. (Decision of 15.01.2019, Case A-004-2017, *3v Sigma*, para. 62)

As no experimentally derived bioconcentration factor values were available it was necessary to consider the screening criteria established in Annex XIII REACH to see if the transformation and/or degradation products are potentially bioaccumulative. (Decision of 15.01.2019, Case A-004-2017, *3v Sigma*, para. 63)

11.5. Animal welfare (Article 25 REACH)

General. The two components of the heading of title III of the REACH Regulation (data sharing and avoidance of unnecessary testing) are not, in principle, indissolubly linked. The requirement to avoid unnecessary testing goes beyond the data sharing requirements. Where ECHA requires additional testing, it must ensure that vertebrate animals are used only as a last resort. Its actions should demonstrably not run counter to the principles of Directive 2010/63/EU. (Decision of 19.06.2013, Case A-005-2011, *Honeywell Belgium*, para. 90, 94, 108 and 110)

With regards to animal welfare, the BoA observed that Article 25(1) REACH provides that testing on vertebrate animals for the purposes of the REACH Regulation shall be undertaken only as a last resort. The BoA considered that the duty to avoid animal testing pursuant to Article 25(1) REACH applies to ECHA, as well as to registrants, when it examines a testing proposal under Article 40 REACH. In this regard, the BoA noted that ECHA's checks of the dossiers of other registrants of the same substance for relevant information is good practice and one practical way for ECHA to help ensure that, pursuant to Article 25(1) REACH, testing on vertebrate animals is undertaken only as a last resort. (Decision of 10.06.2015, Case A-001-2014, *CINIC Chemicals Europe*, para. 75; Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 160; Decision of 29.06.2021, Case A-001-2020, *SNF*, para. 52)

In exercising its discretion, ECHA is required to take into account and balance a number of, sometimes competing, considerations. For the purposes of the present case, those considerations included the need, pursuant to Article 25(1) REACH, to ensure that testing on vertebrate animals is undertaken only as a last resort, and the need for administrative efficiency. (Decision of 10.06.2015, Case A-001-2014, *CINIC Chemicals Europe*, para. 74; Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 128)

Absence of discretion. Once ECHA is justified in rejecting the proposed read-across on the grounds that the conditions of Section 1.5 of Annex XI REACH were not met, ECHA had no discretion as to whether to request the appellant to perform the PNDT study, which is a

standard information requirement. Accordingly, ECHA did not breach the animal welfare requirements in Articles 13(1), 25(1) REACH and recital 47 REACH by requesting a PNDT study. (Decision of 07.10.2016, Case A-017-2014, *BASF*, para. 88-89)

Tonnage downgrade. The refusal by ECHA to assess the tonnage downgrades after notification of a draft compliance check decision might lead to unnecessary studies on vertebrate animals. By refusing to take into account substantial new information after the administrative cut-off point in a compliance check process, ECHA therefore breached its duty to ensure that studies on vertebrate animals are carried out only as a last resort under Article 25(1). (Decision of 09.11.2021, Joined Cases A-006-2020 and A-007-2020, *BASF Colors & Effects and BASF*, para. 76)

12. REACH – DOSSIER EVALUATION

12.1. General

Relationship between Articles 40 and 41 REACH. The procedures under Articles 40 and 41 REACH allow ECHA to assess the quality and adequacy of the information provided by registrants in their registration dossier in order to verify that the information requirements of the REACH Regulation have been fulfilled. The procedures under Articles 40 and 41 REACH, and the follow-up under Article 42 REACH to decisions taken by ECHA under Articles 40 and 41 REACH, ensure that registrants have the possibility to comply with their duties, including providing adaptations instead of vertebrate animal studies whenever possible. (Decision of 09.02.2021, Case A-015-2019, *Polynt*, para. 51; Decision of 23.02.2021, Joined Cases A-016-2019 to A-029-2019, *Lubrizol France and Others,* para. 120-121)

Where it is clear that it was always the registrant's intention not to submit a testing proposal but an adaptation, the ECHA decision should be adopted under the compliance check procedure. (Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 44-45)

The adaptations may, depending on their content, be examined under both Article 40(3) and Article 41(1)(b) REACH. The scope and content of the specific adaptation rules do not vary depending on whether they are applied in a testing proposal procedure or a compliance check procedure. (Decision of 09.02.2021, Case A-015-2019, *Polynt*, para. 51)

The reliance on Article 40 rather than Article 41 REACH as the legal basis for the contested decision did not lead to a different assessment of the appellant's registration dossier for the endpoints in question and would not therefore have led to a different decision. Furthermore, ECHA's error in choice of legal basis did not deprive the appellant of the procedural guarantees set out in the relevant provisions of the REACH Regulation, in particular Articles 50 and 51 REACH. The appellant had not established the existence of any of the alleged adverse consequences. (Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 58)

Cut-off point. ECHA may refuse to take into account information received after a cut-off point set by ECHA. (Decision of 10.06.2015, Case A-001-2014, *CINIC Chemicals Europe*, para. 78; Decision of 07.10.2016, Case A-017-2014, *BASF*, para. 68; Decision of 09.04.2019, Case A-001-2018, *BrüggemannChemical, L. Brüggemann*, para. 66-68; Decision of 09.11.2021, Joined Cases A-006-2020 and A-007-2020, *BASF Colors & Effects and BASF*, para. 49)

> ***Consequence***. If relevant information comes to light during the decision-making process, ECHA may, depending for example on the relevance and importance of the new information, be required to re-start, or repeat certain steps of, the decision-making process. This might be necessary in some cases to ensure that all the relevant actors are given the opportunity to comment on that information, especially if this information has not been generated by the registrant itself. (Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 305-306, referring to Decision of 10.06.2015, Case A-001-2014, *CINIC Chemicals Europe*, para. 90; Decision of 09.04.2019, Case A-001-2018, *BrüggemannChemical, L. Brüggemann*, para. 72)
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> ***Justification for cut-off point***. With the aim of ensuring efficiency in its dossier evaluation processes and to avoid an unreasonable burden, ECHA had introduced a cut-off point after which it will not take into account for the purposes of its decision any additional information that comes to light. The BoA noted that efficiency in the decision-making process means that a greater number of decisions can be adopted by ECHA, registrants can be informed of the results of evaluations more rapidly, and, as a consequence, registration dossiers can be brought into compliance with the requirements of the REACH Regulation at a faster rate. This in turn should result in benefits to the protection of human health and the environment. (Decision of 10.06.2015, Case A-001-2014, *CINIC Chemicals Europe*, para. 76)
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> The cut-off point for dossier update can be justified by the need to provide guarantees for MSCAs and registrants that the information contained in the registration dossier under

evaluation is stable when it has to be examined by the MSCAs. (Decision of 07.10.2016, Case A-017-2014, *BASF*, para. 66)

Competing interests*.* The BoA observed that the cut-off point is not defined in the REACH Regulation. The BoA considered however that practices such as the setting of a cut-off point in a decision-making process may fall within ECHA's margin of discretion. In order to ensure that it has exercised its discretion correctly, however, ECHA must balance the need for administrative efficiency with other relevant considerations such as the need to ensure compliance with Article 25(1) REACH. (Decision of 10.06.2015, Case A-001-2014, *CINIC Chemicals Europe*, para. 78; Decision of 07.10.2016, Case A-017-2014, *BAS*F, para. 67)

The administrative burden alone cannot justify ECHA's departure from the obligations incumbent upon it. The extent of the administrative burden placed on ECHA must also be taken into consideration. The BoA therefore examined whether the administrative burden placed on ECHA was sufficiently excessive to justify, in the interests of administrative efficiency, a departure from the obligations placed on it pursuant to Article 25(1) REACH. (Decision of 10.06.2015, Case A-001-2014, *CINIC Chemicals Europe*, para. 91)

Substantial new information*.* In exercising its discretion, ECHA is required to take into consideration all the relevant factors and circumstances of the situation the act was intended to regulate. ECHA may be required to take into account substantial new information that comes to light before the adoption of the decision in question. In particular, the early assessment of information coming to light after the cut-off point and before the adoption of a decision can serve the objectives of the protection of human health and the environment. Administrative practices designed to facilitate the decision-making process must not operate to frustrate ECHA's obligation to take into account all information. (Decision of 10.06.2015, Case A-001-2014, *CINIC Chemicals Europe*, para. 68-105; Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 152)

As a minimum, substantial new information in a dossier update must be taken into account even if submitted after a draft of the decision has been sent to the MSCAs. (Decision of 09.04.2019, Case A-001-2018, *BrüggemannChemical, L. Brüggemann*, para. 74)

Strict interpretation. After an administrative cut-off point, ECHA may exceptionally limit to substantial new information its obligation to take into account all relevant factors and circumstances of a particular case. As this limitation constitutes an exception to a general obligation of ECHA, it must be applied strictly. (Decision of 09.11.2021, Joined Cases A-006-2020 and A-007-2020, *BASF Colors & Effects and BASF*, para. 54)

Tonnage downgrade. There is no provision in the REACH Regulation that excludes, explicitly or implicitly, the possibility for ECHA to take into account a tonnage downgrade other than a cessation of manufacture or import during a compliance check process. Therefore, ECHA was not legally required to refuse to take into account a tonnage downgrade after the receipt by the registrant concerned of a draft decision in a compliance check process. The refusal to take into account a tonnage downgrade after the receipt by the registrant concerned of a draft decision in a compliance check process was based on an administrative cut-off point established and implemented by ECHA in exercising its discretion. (Decision of 09.11.2021, Joined Cases A-006-2020 and A-007-2020, *BASF Colors & Effects and BASF*, para. 38, 48)

Illustration. ECHA was required to take into account the tonnage downgrades made after the receipt of a draft compliance check decision. First, the downgrades constituted substantial information as the tonnage band determines the applicability of the information requirements set out in Article 12 and Annexes VII to X REACH. Second, the downgrades were new information that was not known until the appellants updated their registration dossiers. ECHA should have examined the tonnage downgrades individually to determine whether they were based on objective industrial or commercial considerations or were primarily triggered by the receipt of the draft compliance check decision and therefore amounted to an abuse of procedure. (Decision of 09.11.2021,

Joined Cases A-006-2020 and A-007-2020, *BASF Colors & Effects and BASF*, para. 55-58 and 74-75)

Illustration. A tonnage downgrade that amounts to an abuse of procedure cannot constitute substantial new information that ECHA is required to take into account after an administrative cut-off point in a compliance check process. A tonnage downgrade may amount to an abuse of procedure if it is not based on objective industrial or commercial considerations. (Decision of 09.11.2021, Joined Cases A-006-2020 and A-007-2020, *BASF Colors & Effects and BASF*, para. 72)

Timing. In Cases A-001-2014 and A-017-2014, the cut-off point for dossier updates set by ECHA was the date on which the draft decision was sent to the MSCAs for their proposals for amendment pursuant to Article 51(1) REACH. In those cases, the BoA found that, for reasons of administrative efficiency, ECHA could apply that particular cut-off point provided that it had mechanisms in place to take into account substantial new information coming to light after that cut-off point. The BoA therefore acknowledged that the obligation to take into account all the relevant factors and circumstances of a particular case may exceptionally be limited to substantial new information after the draft decision has been sent to the MSCAs for their proposals for amendment. This was for reasons of administrative efficiency which includes, in particular, the need for the MSCAs, the MSC and ECHA to have settled facts at a determined time towards the end of the decision-making procedure. In addition, where ECHA follows the decision-making procedure set out in the REACH Regulation without undue delays, the likelihood of substantial new information coming to light after the draft decision has been sent to the MSCAs is reduced. In Case A-001-2018, there was more than an 18-month delay between the appellant commenting on the draft decision and a draft decision being sent to the MSCAs for proposals for amendment. Such a long delay in the decision-making procedure significantly increases the possibility of information coming to light that may affect the final decision. (Decision of 09.04.2019, Case A-001-2018, *BrüggemannChemical, L. Brüggemann*, para. 69-71)

Illustration. In *CINIC*, the information was, first, not known to the registrant at the time of referral of the draft decision to the MSCAs and, second, could have potentially influenced the decision. In this case, the information was, according to the appellant, part of the original registration dossier and thus not new. Further, this information has already been considered by ECHA and found to not affect the draft decision; this information cannot, therefore, be considered to be substantial. (Decision of 07.10.2016, Case A-017-2014, *BASF*, para. 68)

Illustration. In the registration dossier of the appellant the substance type was primarily described as a multi-constituent substance. In the testing proposals the substance was defined as an UVCB substance. The fact that ECHA did not comment on this discrepancy in the contested decision once it had been raised by the appellant does not have any bearing on the fact that in the registration dossier the substance type was primarily described as a multi-constituent substance. Therefore, the appellant's comments on the draft decision as regards the Substance type (UVCB vs multiconstituent) cannot be considered as substantial new information that would require ECHA to re-start, or repeat certain steps of, the decision-making process. (Decision of 29.04.2021, Case A-014-2019, *LG Chem Europe*, para. 60-61)

Presumption of compliance. Prior to a compliance check, a registrant may consider that it had satisfied the relevant information requirements for registration purposes. From the registrant's perspective there would therefore be no reason to update its dossier. It cannot therefore be assumed that a registrant should be aware that its dossier is missing certain information prior to receiving a draft decision and that it needs to update its dossier. (Decision of 09.04.2019, Case A-001-2018, *BrüggemannChemical, L. Brüggemann*, para. 77)

Informal discussions outside the decision-making procedure. There is no rule of law preventing ECHA from discussing with, or seeking information from, registrants outside the procedure set out in Articles 40, 50 and 51 REACH if it so chooses. However, if ECHA requests registrants to provide information outside the formal decision-making procedure set out in Article 40, 50 and 51 REACH, and information is provided as a result, the principle of good

administration requires ECHA to take any information provided into account in its decision. (Decision of 23.02.2021, Joined Cases A-016-2019 to A-029-2019, *Lubrizol France and Others*, para. 78)

Addressees. A decision on a testing proposal under Article 40 REACH must be addressed to all those registrants of the same substance to whom an information requirement applies and who have not decided to submit separately the information in question in accordance with Article 11(3) REACH. As each of the contested decisions was addressed only to the lead registrant for the relevant substance, and not to the other registrants, Articles 40(3) and 50(1) REACH were breached. (Decision of 23.02.2021, Joined Cases A-016-2019 to A-029-2019, *Lubrizol France and Others*, para. 152-169)

12.2. Evaluation of testing proposals (Article 40 REACH)

Third-party consultation. To comply with Article 40(2) REACH, ECHA is required to publish the substance name, the hazard endpoint for which vertebrate testing is proposed and the deadline for responding to the consultation. ECHA is therefore not required by the REACH Regulation to publish details of the actual test proposed by a registrant to meet a specific endpoint. However, whilst it is not legally obliged to do so, ECHA should consider, in certain cases, making third party consultations more explanatory so that all possibly relevant data is made available to ECHA to help it in deciding whether to approve, modify or reject testing proposals. In certain circumstances this could entail publishing in the third-party consultation the actual test proposed, as well as the hazard endpoint in question. This could also contribute to fulfilling ECHA's obligations under Article 25(1) REACH to ensure that testing on vertebrate animals is only undertaken as a last resort. (Decision of 10.06.2015, Case A-001-2014, *CINIC Chemicals Europe*, para. 45 and 48)

Information received from a third-party consultation under Article 40(2) REACH is not necessary to 'fulfil' the information requirement; such an interpretation would go beyond the conditions set out in Article 40(2) REACH. (Decision of 29.04.2021, Case A-014-2019, *LG Chem Europe*, para. 99; Decision of 09.02.2021, Case A-015-2019, *Polynt*, para. 81)

ECHA must take into account scientifically valid information and studies received in a third-party consultation under Article 40(2) REACH. This does not mean that the information received from the third-party consultation under Article 40(2) REACH must fulfil the information requirement or prove that the information requested is not necessary. The information provided by the third parties should not be only observations or statements, but 'scientifically valid information and studies' as referred to in Article 40(2) REACH. If the the third-party comments are not substantiated or accompanied by any documentation, scientific or otherwise, or references to documentation, ECHA is not required to respond to them in detail in the contested decision. (Decision of 09.02.2021, Case A-015-2019, *Polynt*, para. 80-84)

ECHA is only required to check the dossiers of other registrants of the *same* substance for relevant information during a testing proposal decision-making procedure under Article 40 REACH. ECHA is not required to consider information available in the registration dossiers of *any other* substances and publicly available information for other substances that has not been specifically raised by the registrant. (Decision of 24.03.2020, Case A-006-2018, *Emerald Kalama Chemical and Others*, para. 107; Decision of 04.05.2018, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 35; Decision of 29.04.2021, Case A-014-2019, *LG Chem Europe*, para. 67-69)

The testing proposal consultation also included the statement next to the name of the substance, 'Note: testing proposed with [the source substance]'. This additional information is not a requirement of Article 40(2) REACH. However, the appellant did not demonstrate why the provision of this additional information would prevent third parties from providing relevant information on the substance, as alleged by the appellant. On the contrary, it might have encouraged the submission of information on the source substance as well as on the substance if such information was available. (Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 66)

12.3. Compliance checks (Article 41 REACH)

Objectives of compliance check. The objective of a compliance check under Article 41 is not to review the history of a registration dossier with the aim of identifying retroactively the time periods during which a registrant might have been in breach of the obligations described in the previous paragraph. In particular, the objective of a compliance check under Article 41 is not to verify that updates under Article 22(1) were made without undue delay. ECHA's powers in a compliance check under Article 41 aim, first, at identifying the potential data-gaps in the registration dossier under evaluation at the time of the adoption of the compliance check decision and, second, at requiring the submission of the information needed to fill those potential data-gaps. (Decision of 09.11.2021, Joined Cases A-006-2020 and A-007-2020, *BASF Colors & Effects and BASF*, para. 63)

Powers of ECHA. Under Article 41 REACH, ECHA can assess the quality and adequacy of information submitted in a registration dossier in order to determine whether that information satisfies the information requirements set out in the REACH Regulation. (Decision of 29.06.2021, Case A-001-2020, *SNF*, para. 38; Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum*, para. 40; Decision of 25.04.2023, Joined Cases A-002-2022 and A-003-2022, *BASF Lampertheim and Metall-Chemie*, para. 36; decision of 29.08.2022, Case A-006-2022, *Symrise and Others*, para. 33)

ECHA has the power to conduct its own assessment in order to verify whether a submitted study was carried out correctly in accordance with the relevant test method. (Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum*, para. 43)

When the relevant information requirement concerns information on a study, and when that study or an acceptable adaptation has not been submitted by the registrant, ECHA's powers are limited to verifying whether there is a data-gap in the registrant's dossier. (Decision of 29.06.2021, *SNF,* Case A-001-2020, para. 39; Decision of 19.01.2021, *Croda Iberica*, para. 60; Decision of 04.05.2018, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 49-51)

Under Article 41(1)(a) the Agency has competence to examine whether any registration complies with the requirements set out in Articles 10, 12, 13 and Annexes III and VI to X. Article 41(3) empowers the Agency to request from a registrant any information that is needed to bring the registration into compliance with the information requirements set out in the REACH Regulation. (Decision of 21.06.2023, Case A-004-2022, *Symrise*, para. 44-45)

Article 41(1)(a) empowers the Agency to examine whether the registration complies not only with the specified Annexes, but also with, amongst other provisions, Article 13(3). (Decision of 21.06.2023, Case A-004-2022, *Symrise*, para. 50)

Absence of discretion. The requirements in a compliance check decision are not discretionary requests for further information, such as those which ECHA adopts in the context of the substance evaluation procedure under Article 46 REACH. They are the direct and automatic consequence of ECHA's finding of a data-gap, flowing from Article 41 REACH in conjunction with Articles 10(a) and 13(1) REACH. (Decision of 11.12.2018, Case A-006-2017, *Climax Molybdenum*, para. 118-121)

If it has correctly identified the existence of a data-gap, ECHA is neither required nor empowered to consider whether it is consistent with the principle of proportionality, or with Article 25 REACH, for a registrant to be required to submit the required test or an acceptable adaptation (Decision of 04.05.2018, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 51; Decision of 07.09.2021, A-008-2020, *Sustainability Support Service (Europe)*, para. 65)

If ECHA finds that a read-across adaptation does not comply with the rules set out in Section 1.5. of Annex XI REACH, it must require the registrant to perform the relevant test or an acceptable adaptation in order to satisfy the information requirements established in the REACH Regulation. (Decision of 19.10.2016, Case A-004-2015, *Polynt*, para. 118; A-006-2018, *Emerald Kalama Chemical and Others,* para. 77)

Once ECHA rejected the proposed adaptation it enjoyed no margin of discretion as to whether to request a sub-chronic toxicity study and a pre-natal developmental toxicity study. Consequently, it did not breach the principle of proportionality by requesting the studies to be performed. (Decision of 30.01.2018, Case A-005-2016, *Cheminova*, para. 169)

Application of the principle of proportionality and Article 25. Where the Agency has a power of discretion as to the measure to be taken, it must ensure that the measure it chooses is proportionate.13 Where it has no such power of discretion, because the measure to be taken has been determined by the legislature, the Agency is neither required nor empowered to examine the proportionality of the measure, that assessment being reserved to the EU Courts in accordance with Article 277 of the Treaty on the Functioning of the European Union (TFEU). (Decision of 19.09.2023, Case A-009-2022, *Nouryon Functional Chemicals and Others*, para. 33 [currently subject to appeal before the General Court])

The consequences of the existence of a data-gap flow directly from the REACH Regulation. Under Article 10(a)(vi), read in conjunction with Section 8.7. of Annex IX and Annex XI, the Appellants are obliged to submit either information on an OECD TG 443 study or, alternatively, an acceptable adaptation in accordance with the specific adaptation rules in Column 2 of Section 8.7.3. of Annex IX or the general adaptation rules in Annex XI. In the present case, the Appellants did not provide an acceptable adaptation based on Column 2 of Section 8.7.3. of Annex IX, or an adaptation under the general rules for adaptation set out in Annex XI. Therefore, the Agency was neither required nor empowered to consider whether it is consistent with Article 25 for the Appellants to be required to submit this information. (Decision of 29.08.2023, Case A-006-2022, *Symrise and Others*, para. 75)

Responsibility of registrants. It is the sole responsibility of registrants to generate, gather and submit to ECHA the information that they consider will fulfil the information requirements of the REACH Regulation. ECHA correctly limited its examination to the information submitted by the appellant in the relevant parts of its registration dossier, in accordance with the relevant provisions of the REACH Regulation (Articles 10(a)(vii) and 14(1), and Annex I). (Decision of 29.06.2021, Case A-001-2020, *SNF*, para. 47; Decision of 29.08.2023, Case A-006-2023, *Symrise and Others*, para. 46)

Deadline for providing required information. Under Article 41(3) the Agency must specify an adequate time limit allowing the registrant concerned to bring its registration dossier into compliance, that is to say to fill the data-gaps identified by the Agency in a compliance check decision. For each data-gap identified in such a compliance check decision, the registrant concerned must submit information on the study requested or, alternatively, an acceptable adaptation. (Decision of 21.06.2023, Case A-004-2022, *Symrise*, para. 147; Decision of 09.11.2021, Case A-009-2020, *Polynt*, para. 44)

Irrespective of any time limit, it is for the Appellant to take appropriate measures following the adoption of the Contested Decision to start carrying out a mutagenicity study or developing an adaptation if it considered that it could lead to the possibility of adapting the PNDT study and the EOGRTS. The Appellant has not only the right but also the obligation to do so in order to avoid unnecessary vertebrate animal testing under Article 25 whenever possible. (Decision of 21.06.2023, Case A-004-2022, *Symrise*, para. 154)

No obligation to wait for information before adopting decision. The Agency was entitled to require the Appellants to submit information on an EOGRTS without extending the time limit set in the Contested Decision to allow for the investigation of the effects of the Substance on the gut microbiome. The Agency was not obliged to wait for the Appellants to generate information not falling within the scope of the information requirements set out in the testing Annexes. (Decision of 29.08.2023, *Symrise and Others*, A-006-2022, para. 37)

The Agency's assessment (under COlumn 1 of Section 8.7.3. of Annex IX) is based on information which is currently available. If the information which is currently available is sufficient to meet at least one of the conditions of Column 1 of Section 8.7.3. of Annex IX the Agency does not have the obligation to wait for a registrant to generate further information before adopting its decision. (Decision of 19.09.2023, Case A-009-2022, *Nouryon Functional Chemicals and Others*, para. 38 [currently subject to appeal before the General Court])

12.4. Follow-up procedure

Possibility to submit adaptations following an initial dossier evaluation ('DEv') decision. Registrants may submit adaptations not only in their registration dossiers in lieu of the results from a study, but also in testing proposals and in the follow-up under Article 42 REACH to decision taken by ECHA under Articles 40 or 41 REACH. (Decision of 23.02.2021, Joined Cases A-016-2019 to A-029-2019, *Lubrizol France and Others,* para. 63 and 122; Decision of 04.05.2020, Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, para. 52)

Article 42(1) REACH was the correct legal basis for the contested decision consisting of an examination of the information submitted by a registrant in consequence of an ECHA decision taken under Article 41 REACH and the drafting of an appropriate decision. (Decision of 21.10.2020, Case A-001-2019, *Solvay Fluor*, para. 37-38)

The second sentence of Article 41(3) REACH refers to the decision-making procedure laid down in Articles 50 and 51 REACH. As confirmed by the General Court, that procedure applies equally to the adoption of an initial compliance check decision and to the adoption of a follow-up compliance check decision under Article 42(1) REACH. (Decision of 21.10.2020, Case A-001-2019, *Solvay Fluor*, para. 64)

No obligation to set a new time-limit. At the stage of the adoption of a follow-up compliance check decision under Article 42(1) REACH, ECHA does not have to require the registrant to submit further information to that which was already identified as missing in the initial compliance check decision. The adoption of a follow-up compliance check decision under Article 42(1) REACH is the result of a check carried out by ECHA that '*is merely the continuation of the same, single procedure*' concerning the same data-gap and the same information requirement. Therefore, the requirement to specify adequate time limits in the second part of the first sentence of Article 41(3) REACH is not relevant to the adoption of a follow-up compliance check decision under Article 42(1) REACH. (Decision of 21.10.2020, Case A-001-2019, *Solvay Fluor*, para. 61-62)

A follow-up decision under Article 42(1) is strictly limited to assessing whether the data-gaps identified in the initial compliance check decision have been filled. Article 42(1) does not oblige the Agency to set a new deadline. (Decision of 23 August 2022, *Celanese Production Germany*, A-004-2021, para. 149)

Request for further information after an initial compliance check decision. The adoption of an initial compliance check decision does not prevent ECHA from identifying, at a later stage, in the same registration dossier, other data-gaps that are different from the data-gaps identified in the initial compliance check decision. However, in such a case, ECHA must start a new compliance check process under Article 41 REACH, and cannot base its examination of those potential new data-gaps on Article 42(1) REACH. The follow-up process under Article 42(1) is strictly limited to an assessment of whether the data-gaps identified in the initial compliance check decision have been filled. ECHA cannot request further information in a follow-up compliance check decision adopted under Article 42(1). Any request for further information, after the adoption of an initial compliance check decision, must be based on a new compliance check process under Article 41. (Decision of 09.11.2021, Case A-009-2020, *Polynt* [currently subject to appeal before the General Court], para. 47-48)

13. REACH – SUBSTANCE EVALUATION

13.1. General

Objectives. The substance evaluation process, as one of the pillars of the REACH regulatory system, greatly contributes to the aim of the protection of human health and the environment. (Decision of 27.10.2015, Case A-006-2014, *International Flavors & Fragrances*, para. 44)

The objective of substance evaluation under the REACH Regulation is to allow, inter alia, for the generation of more information on the properties of a substance that is considered to constitute a risk to human health or the environment. (Decision of 27.10.2015, Case A-006-2014, *International Flavors & Fragrances*, para. 46; Decision of 23.09.2015, Case A-005-2014, *Akzo Nobel and Others*, para. 56-58)

This is essential in order to attain the main objective of the REACH Regulation, which is to achieve a high level of protection of human health and the environment (Decision of 06.08.2018, *SI Group UK and Others*, Case A-006-2016, para. 51)

The aim of substance evaluation is to clarify uncertainty. Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 95; Decision of 15.01.2019, Case A-004-2017, *3v Sigma*, para. 56)

Discretion. If ECHA is to be able to pursue effectively its role under the REACH Regulation, and in particular in the framework of substance evaluation, account being taken of the technical assessments which it must undertake, ECHA must be recognised as enjoying a broad discretion. The exercise of that discretion is not, however, excluded from review by the BoA. (Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 41)

Burden of proof at the stage of the initial decision. The burden of proof under the substance evaluation process rests on ECHA. ECHA must demonstrate, when requiring further information on a substance, that the request is necessary. At that stage, it is not for the registrant to prove that there is no concern. (Decision of 29.01.2020, Case A-008-2018, *Taminco and Performance Additives Italy,* para. 87)

13.2. Conditions for requiring further information (three-prong test)

13.2.1. General

'Three-prong test'. Substance evaluation is intended to assess risks that may occur in reality and not purely theoretical risks. Under substance evaluation, in order to request additional information consistent with the proportionality principle, ECHA must inter alia be able to demonstrate the necessity of the requested measure by setting out the 'grounds for considering that a substance constitutes a risk to human health or the environment'. ECHA must also be able to demonstrate that the potential risk needs to be clarified, and that the requested measure has a realistic possibility of leading to improved risk management measures. This approach is consistent with the EU Courts' interpretation of the precautionary principle which states that 'a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time the measure was taken'. (Decision of 27.10.2015, Case A-006-2014, *International Flavors & Fragrances*, para. 75-77; Decision of 12.07.2016, Case A-009-2014, *Albemarle Europe*, para. 71-72; Decision of 19.12.2016, Case A- 018-2014, *BASF*, para. 269 and 432; Decision of 12.01.2021, Case A-007-2019, *Chemours Netherlands*, para. 38-40; Decision of 10.05.2021, Case A-002-2021, *Lanxess Deutschland and Schirm*, para. 89; Decision of 22.03.2022, Case A-003-2020, *Campine Belgium*, para. 108; Decision of 22.03.2022, Case A-004-2020, *Tribotecc Austria*, para. 108; Decision of 22.02.2022, Case A-005-2020, *S. Goldmann & Co. Germany*, para. 106)

To demonstrate the necessity of a request for information under substance evaluation, the Agency must establish that: (i) there are grounds for considering that, based on a combination of information on potential hazard and potential exposure, a substance constitutes a potential

risk to human health or the environment; (ii) the potential risk needs to be clarified; and (iii) the requested information, needed to clarify the concern, has a realistic possibility of leading to improved risk management measures. (Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 75)

Under the substance evaluation procedure greater clarity regarding the potential risks to human health and the environment is required in order to substantiate a request for further information. ECHA must be able to demonstrate that there is a potential risk, that this risk needs to be clarified, and that the requested information has a realistic possibility of leading to improved risk management measures. If these conditions cannot be met the information requested would not meet real information needs for the protection of human health and the environment pursuant to substance evaluation. (Decision of 23.09.2015, Case A-005-2014, *Akzo Nobel and Others*, para. 73; Decision of 08.09.2017, Case A-026-2015, *Envigo and DJChem*, para. 41-42)

Substance evaluation is intended to assess risks that may occur in reality and not only theoretically. The primary objective in the REACH Regulation of the protection of human health and the environment would not be served by requests for the generation of information that would not meet 'real information needs'. Additionally, the competitiveness of EU industry, another objective of the REACH Regulation, although subordinate to the protection of human health and the environment, would be compromised by incurring costs for tests which do not satisfy 'real information needs'. ECHA must therefore be able to demonstrate, secondly, that the potential risk identified needs to be clarified. Thirdly, ECHA must be able to demonstrate that the information requested has a realistic possibility of leading to improved risk management measures. (Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 60)

Quality and quantity of the available information. ECHA must take into account all the available evidence before deciding, based on that evidence as a whole, that there is a potential risk which requires further investigation. ECHA must give due consideration to the quality and quantity of information both in support of the potential risk and against the existence of that potential risk. (Decision of 30.06.2017, Case A-015-2015, *Evonik Degussa and Others*, para. 123; Decision of 10.02.2020, Joined Cases A-003-2018, A-004-2018 and A-005-2018, *BASF and Others*, para. 88)

No limitation to reasons for CoRAP inclusion. The processes of establishing the CoRAP and the evaluation of a substance included in the CoRAP are separate, although linked, processes. The process establishing the CoRAP relies on risk-based criteria which are used to select substances for inclusion in the CoRAP. Inclusion in the CoRAP means that the substance will subsequently be evaluated pursuant to the substance evaluation process. The REACH Regulation does not require that the relevant risk based criteria which lead to the inclusion of a substance in the CoRAP needs to be identified in the CoRAP. While it is ECHA's practice to indicate in the CoRAP the concern(s) that led to a substance's inclusion therein, the identification of initial grounds for concern cannot be interpreted as restricting or limiting the scope of the substance evaluation process. Such an approach would ignore any new concerns which are identified after the substance evaluation procedure began, and so potentially overlook threats to human health or the environment. (Decision of 27.10.2015, Case A-006-2014, *International Flavors & Fragrances*, para. 48-49)

The priority setting exercise for substances to be included in CoRAP must identify those substances that potentially pose a risk to human health and the environment. The subsequent assessment of substances in CoRAP is not limited to the concern(s) that led ECHA to include that substance in CoRAP in the first place. (Decision of 27.10.2015, Case A-006-2014, *International Flavors & Fragrances*, para. 55)

Identification of the substance subject to information request. The clear identification of the substance or substances subject to a request for information under the substance evaluation process constitutes an essential precondition for the application of the three conditions [for requesting information under substance evaluation]. It is in relation to each substance specifically that it is necessary to examine whether a potential risk for human health or the environment exists (Case A-003-2020, *Campine Belgium*, para. 121; Decision of

22.03.2022, Case A-004-2020, *Tribotecc Austria*, para. 121; Decision of 22.02.2022, Case A-005-2020*, S. Goldmann & Co. Germany*, para. 119 quoting judgment of 15.09.2021 in case T-127/20, *France* v *ECHA*, para. 45-46.)

Request for information following a second substance evaluation. The third sentence of Article 47(1) sets out a specific threshold for the evaluation of a substance which has previously been subject either to a decision on a testing proposal or on dossier evaluation under Article 51 or to a decision on substance evaluation under Article 52. In other terms, as regards substance evaluation, it is only in cases where a decision under Article 52 has been previously taken on a substance that the conditions set out in the third sentence of Article 47(1) apply to a potential new evaluation of the same substance. If an evaluating competent authority issues 'conclusions' on a substance evaluation without a decision being taken under Articles 51 and 52, this does not prevent such a decision being taken at a later stage (Article 47(1), third sentence). This issuance of such conclusions also does not give registrants legitimate expectations that no decision will be taken following a new substance evaluation. (Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 37, 39, 49)

13.2.2. Potential risk

General. Under substance evaluation, in order to request additional information ECHA must be able to, firstly, demonstrate that there is a potential risk to human health or the environment. With the objective in the REACH Regulation regarding protection of human health and the environment in mind, proof of a real risk is too high a threshold to meet. Nevertheless, ECHA must be able to demonstrate the presence of a potential risk. (Decision of 23.09.2015, Case A-005-2014, *Akzo Nobel and Others*, para. 59; see also Decision of 29.01.2020, Case A-008-2018, *Taminco and Performance Additives Italy,* para. 66)

This does not mean however that any evidence of a potential concern, no matter how weak, is sufficient to justify such a request. (Joined Cases A-003-2018, A-004-2018 and A-005-2018, Decision of 10.02.2020, *BASF and Others*, para. 87)

To request information under substance evaluation, it is not necessary for the Agency to demonstrate an actual risk, only a potential risk. The aim of requesting additional information under substance evaluation is to clarify the risk. This is consistent with the different types of risk that must be taken into account at different stages of the processes established by the REACH Regulation. This is also consistent with the European Union Courts' interpretation of the precautionary principle according to which 'a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time the measure was taken'. A request for further information under substance evaluation cannot be triggered by a purely hypothetical risk or by a failure to prove the lack of any risk. It is the Agency's responsibility to justify a request for further information under substance evaluation by demonstrating that the three conditions of the necessity test are met. A request for further information under Substance evaluation cannot be triggered by a purely hypothetical risk or by a failure to prove the lack of any risk. (Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 76-80)

The identification of a potential risk is based on a combination of hazard and exposure information. (Decision of 23.09.2015, Case A-005-2014, *Akzo Nobel and Others*, para. 61; Decision of 28.06.2016, Case A-015-2014, BASF, para. 58; Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 214; Decision of 12.01.2021, Case A-007-2019, *Chemours Netherlands*, para. 38, 47; Decision of 22.03.2022, Case A-003-2020, *Campine Belgium*, para. 108, 127; Decision of 22.03.2022, Case A-004-2020, *Tribotecc Austria*, para. 108, 127; Decision of 22.02.2022, Case A-005-2020*, S. Goldmann & Co. Germany*, para. 106, 125; Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 84)

In assessing whether there is a potential risk, where there is high potential exposure to a substance the evidence of a potential hazard may be correspondingly less. (Decision of 30.06.2017, Case A-014-2015, *Grace*, para. 57; Decision of 30.06.2017, Case A-015-2015, *Evonik Degussa*, para. 82; Decision of 30.06.2017, Case A-015-2015, *Evonik Degussa*, para. 82)

Potential vs actual risk. Under Article 46 REACH, ECHA is not required to demonstrate an *'actual risk'* but only a *'potential risk'*. The aim of requesting additional information under substance evaluation is to clarify whether the potential risk is an actual risk. (Decision of 17.12.2019, Joined Cases A-003-2018, A-004-2018, and A-005-2018, *BASF and Kemira*, para. 84 to 87; Decision of 22.03.2022, Case A-003-2020, *Campine Belgium*, para. 110; Decision of 22.03.2022, Case A-004-2020, *Tribotecc Austria*, para. 110; Decision of 22.02.2022, Case A-005-2020, *S. Goldmann & Co. Germany*, para. 108; Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 76)

This is consistent with the different types of risk that must be taken into account at different stages of the processes established by the REACH Regulation, and with the precautionary principle. (Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 77, 78)

> ***Illustration.*** ECHA did not examine the available information in order to clarify whether there is an actual risk for carcinogenicity and the appropriate classification for the substance. ECHA rather examined the available information and concluded that there was a potential risk for carcinogenicity which would justify requesting additional information aimed at clarifying the carcinogenicity concern. (Decision of 12.01.2021, Case A-007-2019, *Chemours Netherlands*, para. 75, 77)
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> ***Illustration***. It was undisputed that an experimental study on animals is well-performed and shows that the Substance induces benign and malignant tumours. According to the CLP Regulation, there is then a presumption that those tumours are relevant for humans unless there is 'strong evidence' that the modes of action linked to the tumour formation are not relevant for humans. Even if it is demonstrated that a specific mode of action is relevant to the formation of the tumours observed in a particular study, the registrant must not only show that that mode of action is not relevant to humans but also that there is no other mode of action that may be relevant to humans. (Decision of 12.01.2021, Case A-007-2019, *Chemours Netherlands*, para. 53-54, 58, 62, 69-71)

Potential exposure. The examination of exposure for the purposes of demonstrating a potential risk is not the same as the examination of exposure for the purposes of demonstrating a realistic possibility of improved risk management measures. Demonstrating a realistic possibility of improved risk management measures involves an examination of whether the population(s) concerned by the exposure may benefit from further protection through improved risk management measures as a result of the information requested under the substance evaluation process. Examination of potential exposure involves an examination of whether there is potential exposure to a substance irrespective of the controls in place. (Decision of 22.03.2022, Case A-003-2020, *Campine Belgium*, para. 143: Decision of 22.03.2022, Case A-004-2020, *Tribotecc Austria*, para. 144; Decision of 22.02.2022, Case A-005-2020, *S. Goldmann & Co. Germany*, para. 142)

The examination of exposure for the purposes of demonstrating a potential risk is not the same as the examination of exposure for the purposes of demonstrating a realistic possibility of improved risk management measures. (Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 102)

Specific vs general concern. ECHA could not rely on a general concern regarding surface-treated substances that are also nanomaterials. ECHA must be able to demonstrate a specific concern in relation to the substance at issue. (Decision of 30.06.2017, Case A-014-2015, *Grace*, para. 134; Decision of 30.06.2017, Case A-015-2015, *Evonik*, para. 189)

Nanomaterial. Being a nanomaterial is insufficient on its own to justify a potential concern under substance evaluation. Some nanomaterials are hazardous whilst others are not. Nanomaterial is a categorisation of a substance by its size. However, the fact that a substance is a nanomaterial neither implies a specific risk nor does it necessarily mean that the substance has different hazard properties compared to its non-nano 'form'. Furthermore, no consistent causal link has yet been established between size and hazardous properties. Furthermore, the definition of nanomaterials establishes a size threshold for substances to be nanomaterials. The definition does not however mean that substances below the threshold are per se more

hazardous than those above this threshold. (Decision of 30.06.2017, Case A-014-2015, *Grace*, para. 65; Decision of 30.06.2017, Case A-015-2015, *Evonik Degussa*, para. 105)

Monomer in polymers. The appellants argued that the contested decision had failed to establish, and explain, the existence of a potential risk with regard to each individual polymer on which information is requested. The BoA noted that the information requirements arose from the evaluation of the respective monomer l, not the evaluation of each individual polymer made from that monomer. ECHA is consequently not required to establish, or explain, the existence of a potential risk with regard to each individual polymer but only for the monomer. (Decision of 06.08.2018, Case A-006-2016, *SI Group UK and Others*, para. 127-128)

Study limitations (reliability/relevance). Whilst a study of unknown reliability may provide grounds for concern it may not on its own be sufficient to request information under substance evaluation. (Decision of 12.07.2016, Case A-009-2014, *Albemarle Europe*, para. 102; see also Decision of 30.06.2017, Case A-014-2015, *Grace*, para. *110, 123, 128 and 133;* Decision of 30.06.2017, Case A-015-2015, *Evonik Degussa*, para. 165-166 (weak evidence – relatively high dose levels), 176 (short-term studies), 181 (lack of dose/response assessment and lack of clarity on exposure substance and duration))

Although the acknowledged deficiencies in the studies relied on by ECHA reduced their reliability, it was nonetheless possible under substance evaluation that such studies could be sufficient to demonstrate a concern. However, ECHA must carefully justify any decision to rely on studies with limited reliability to override the results of reliable, high quality studies with negative results. ECHA had not provided an adequate justification for relying on positive results from less reliable *in vitro* and *in vivo* studies against the negative results from the more reliable *in vitro* studies provided by the appellants. (Decision of 10.02.2020, Joined Cases A-003-2018, A-004-2018 and A-005-2018, *BASF and Others*, para. 108)

RCR close to 1. it is necessary for RCRs to be below 1 in order to demonstrate safe use. However, just because a RCR is close to 1 does not mean that the exposure in practice is close to that which could lead to effects on health. Sometimes RCRs are close to 1 because the registrant concerned wants to explore the limits of exposure whilst putting far more protective measures in place, for example, shorter periods of exposure, more effective extraction systems, or better protective equipment. Furthermore, establishing a RCR close to 1 can serve as a warning that further safety measures may need to be adopted and actually benefit the protection of human health. In some chemical safety reports registrants may have made certain assumptions, for example modifying safety factors and identifying unrealistic protective measures, to ensure a RCR is below 1. In such cases ECHA may be able to justify why additional information is needed pursuant to a substance evaluation. (Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 66)

Analogue substances. The test for establishing structural similarity for the purposes of identifying grounds for concern under substance evaluation is not the same as that for the use of read-across pursuant to Section 1.5 of Annex XI. The structural similarity of the substances is relevant to the identification of grounds for concern. ECHA might be required to provide additional reasoning to justify the grounds for concern if there were evidence to the contrary regarding the PBT and vPvB properties of the substance. The appellants argued that the substances are not structurally similar but did not present evidence indicating the absence of the PBT/vPvB concerns identified. The BoA found that the structural similarity between the two substances was sufficient, coupled with the environmental exposure to the substance, to demonstrate that the substance may be a PBT or vPvB and may pose a risk to the environment. (Decision of 12.07.2016, Case A-009-2014, *Albemarle Europe*, para. 78-81)

Use of screening studies. The purpose of screening studies is not to identify whether a substance has a particular intrinsic property but to identify those substances which are unlikely to have a particular property the objective being to avoid unnecessary testing. In this case, the results of the screening studies included in the appellants' registration dossiers did not exclude that the substance may be persistent. From this, in the absence of any further information, it can be logically concluded that the substance might be persistent in the environment. (Decision of 08.09.2017, Case A-026-2015, *Envigo and DJChem*, para. 50)

Use of epidemiological studies. When examining the available evidence from the two epidemiological studies it must be borne in mind that there can be confounding factors to consider in the assessment of any epidemiological study. The relevance of the results may also be uncertain especially when the target groups may be, as in the present case, exposed to many different chemicals. (Decision of 27.10.2015, Case A-006-2014, *International Flavors & Fragrances*, para. 97; Decision of 29.01.2020, Case A-008-2018, *Taminco and Performance Additives Italy*, para. 74)

13.2.3. Need to clarify the potential risk

No obligation to wait for the completion of ongoing studies. Imposing an automatic obligation on ECHA to suspend its proceedings each time a new study is conducted or planned, whose timing and relevance are uncertain, could run counter to the primary objectives of the REACH Regulation as it could lead to substance evaluation procedures being significantly delayed. (Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 81)

13.2.4. Possibility of improved risk management measures

Assessment of existing RMMs. The sections of the contested decisions concerning the contested information requirement contain no examination of the available information on uses of the three substances and the RMMs already in place for those substances. In other words, it is not explained in the contested decisions why exposure to the three substances is not already adequately controlled even if the three substances are eventually shown to be genotoxic. Consequently, even if the results of the requested study led, for example, to a new classification, there is no examination in the contested decisions on whether the RMMs stemming from such a classification are already in place. (…)

If workers are a population of concern, there is no examination in the contested decisions of the available information on worker exposure to the three substances and the existing RMMs in relation to the concern for genotoxicity. With regards to oral exposure of workers to the three substances, the contested decisions stated that '*dermal exposure may occur in workers*'. At the hearing, ECHA and the eMSCA argued that there is a concern that workers could ingest the three substances by hand to mouth exposure after dermal exposure. However, ECHA did not demonstrate how the RMMs in place, for example wearing of gloves and washing hands after use, do not already address the concern. (Joined Cases A-003-2018, A-004-2018 and A-005-2018, Decision of 10.02.2020, *BASF and Others*, para. 130, 133-134)

The fact that operational conditions and risk management measures are currently applied in industrial plants to minimise exposure does not mean that other or further risk management measures could ensue. Such improved risk management measures may, amongst others, include revised waste-water discharge conditions, identification as a substance of very high concern (SVHC) with the obligation to notify the SVHC to the Agency under Article 7(2) and communicate about it in the supply chain under Articles 31 and 33. Such identification could in turn, amongst others, lead to revised classification and labelling, introducing a restriction on the use of resorcinol under Title VIII or an authorisation requirement under Title VII. (Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 121, 122)

Request for information on uses. Information on uses may be relevant information to request pursuant to a substance evaluation. However, it must be clear how the requested information on uses will be used to clarify the concern, particularly with regards to improved risk management measures. (Decision of 30.06.2017, Case A-014-2015, *Grace*, para. 196-197; Decision of 30.06.2017, Case A-015-2015, *Evonik Degussa*, para. 289-290)

Inclusion of a substance on the candidate list of substances of very high concern. Identification of a substance as being of very high concern as such is an improved risk management measure. The inclusion of a substance on the candidate list is a means of enhancing the protection of human health and the environment, as it improves information for the public and professionals regarding the risks incurred. Substances from the candidate list may be included to the Annex XIV REACH ("List of substances subject to authorisation"). After such an inclusion, the substance may be subject to controls on its use and eventually it may

be phased out. Therefore, if the requested study may lead to identification of the substance as a substance of very high concern there is a realistic possibility of at least one improved risk management measure. (Decision of 12.01.2021, Case A-007-2019, *Chemours Netherlands*, para. 103-104)

13.3. Other requirements

Appropriateness. A measure is appropriate if it is capable of achieving its objective (Decision of 06.06.2018, Case A-006-2016, *SI Group UK and Others*, para. 100 and the case-law cited). Therefore, in order to demonstrate the appropriateness of an information request in the context of substance evaluation, ECHA must be able to establish that the potential risk posed by the substance can be clarified by the requested information. (Decision of 15.01.2019, Case A-004-2017, *3v Sigma*, para. 88; Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 83)

> ***Illustration***. The BoA dismissed the appellant's argument that using a temperature of 20°C in a simulation test was not appropriate because it is unrealistic. The BoA noted that (1) the aim of the study is not to mimic real-life environmental conditions, (2) a temperature of 20°C is in accordance with the OECD TG, (3) 20°C is not unrealistic for surface water and sediments in certain parts of the EU at certain times of year, and (4) the (higher) temperature of 20°C results in a faster rate of formation of the transformation and/or degradation products which should make the identification of these products, the objective of the study, easier. (Decision of 15.01.2019, Case A-004-2017, *3v Sigma*, para. 90-93)
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> ***Illustration***. ECHA had not precisely itemised the information that it needed in order for the appellant to comply with the information request. ECHA has not, at this point in time, established that UVASORB HEB or its transformation and/or degradation products should be identified as PBT or vPvB according to Annex XIII REACH. As a result, ECHA has failed to demonstrate the necessity for, and the appropriateness of, the requested information. (Decision of 15.01.2019, Case A-004-2017, *3v Sigma*, para. 132)
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> ***Illustration****:* Whilst the BoA accepted that there are differences in the response of rats and humans to exposure to the substance, this was not sufficient to demonstrate that the requested study will not provide useful information on the effects of the substance on exposed humans. (Decision of 19.12.2016, Case A-018-2014, *BASF*, para. 165)
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> ***Illustration.*** Under substance evaluation, ECHA can request information on 'forms' of a substance as long as it can, inter alia, demonstrate that this information will assist in the clarification of the potential concern identified. However, whilst requesting information on 'forms' under substance evaluation is not unlawful per se, the BoA noted that any request for additional information must assist in the clarification of the potential concern and, in addition, satisfy other legal requirements, including the principle of proportionality. (Decision of 30.06.2017, Case A-015-2015, *Evonik Degussa*, para. 200-202)
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> ***Illustration.*** ECHA had requested a Larval Amphibian Growth and Development Assay ('LAGDA'; OECD TG 241) to clarify an endocrine disruption concern through the (anti)androgenic and (anti)estrogenic ('EA') modes of action and the thyroid mode of action. BoA held that ECHA had failed to demonstrate that it was necessary to clarify the endocrine disruption concern through the EA modes of action. BoA then annulled the contested decision, and remitted the case to ECHA, as ECHA had not assessed the relevance and appropriateness of alternative testing methods to the LAGDA in assessing only the thyroid mode of action. (Decision of 10.05.2021, Case A-002-2021, *Lanxess Deutschland and Schirm,* para. 105-114)
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> ***Illustration.*** A Larval Amphibian Growth and Development Assay ('LAGDA'; OECD TG 241) is appropriate to examine the potential endocrine disrupting properties of a substance (Decision of 17.01.2023, Case A-009-2021, *SCAS Europe*, para. 111-116)

The principles of proportionality and legal certainty require that a substance evaluation decision cannot oblige registrants to provide information which they can neither assuredly obtain nor

generate themselves. (Decision of 06.08.2018, *SI Group and Others*, Case A-006-2016, para. 102)

Modification of recognised test methods. Under substance evaluation it may be appropriate to make alterations to recognised test methods, for example, the examination of parameters which do not need to be examined to meet standard information requirements. This helps ensure that information generated pursuant to a substance evaluation decision meets real information needs. (Decision of 23.09.2015, Case A-005-2014, *Akzo Nobel and Others*, para. 88; Decision of 12.07.2016, Case A-009-2014, *Albemarle Europe*, para. 156; Decision of 25 September 2018, Case A-008-2017, *SI Group-UK*, para. 91)

In order to request a test under the substance evaluation procedure, ECHA is not obliged to replicate the tests used as evidence to establish a ground for concern in order to verify its findings. (Decision of 12.07.2016, Case A-009-2014, *Albemarle Europe*, para. 165)

The requests for further information must be fulfilled not only as regards the request for a study as such, but also as regards any specific additional requirements imposed for the conduct of that study. (Decision of 14.12.2021, A-007-2021, *Global Product Compliance (Europe)*, para. 36)

No recognised OECD test method. Under Article 46 REACH, ECHA may require a test to be carried out through any suitable methodology. The absence of officially adopted OECD test guidelines does not in itself mean that the results of a test will not contribute to the clarification of the concern identified. Test methods that have not (yet) been officially adopted or agreed may still be able to clarify a hazard. For example, a test method may address such a niche effect that it has not been considered for adoption by the OECD. This does not mean however that the test is not relevant to the assessment of that hazard. (Decision of 06.08.2018, *SI Group and Others*, Case A-006-2016, para. 174)

Modification based on a study with controversial reliability. The BoA found that a study which deviated from the criteria established in OECD TG 307 was sufficiently rigorous and had a sufficiently solid scientific basis for its results on the substance in question. . The study contributed to clarifying the basis for the formation of transformation products which may have PBT/vPvB properties and could therefore be considered to be a valid an relevant source of evidence. The reliability of the study could be disputed by its deviation from the criteria established in OECD TG 307. (Decision of 12.07.2016, Case A-009-2014, *Albemarle Europe*, para. 159-166)

Discretion left to the registrant in the conduct of the requested study. Absolute certainty in ECHA decisions on complex testing requirements is both impossible and undesirable. (…) It is not a legal flaw in a decision of ECHA if a margin of discretion is granted to the companies involved as this is often a necessity in the conduct of complex tests addressing complex issues. An ECHA decision does however need to be clear in terms of the objectives pursued by the requested tests and to set-out important parameters for the conduct of those tests. (…) Whilst the contested decision lacked clarity on certain aspects of the requested test, and in particular the modifications to OECD TG 307, this lack of clarity was not sufficient to justify an annulment of the contested decision. (Decision of 12.07.2016, Case A-009-2014, *Albemarle Europe*, para. 180-188)

The test to be applied to the assessment of the appropriateness of a measure is not whether the measure in question is the most appropriate to achieve an objective, but whether it is capable of achieving the objective in question. (Decision of 19.12.2016, Case A-018-2014, *BASF*, para. 106)

There are no legal grounds to annul an obligation simply because it is predicated upon its technical feasibility. (…) The use of terms such as '*reasonable attempts*' and '*analytical sensitivity permitting*' to deal with uncertainty could therefore not be deemed to be unlawful in itself. If a particular legal requirement, such as in the requirement to quantify transformation products of the substance '*down to 0.1%*', contains an inherent degree of uncertainty, a conditional obligation can be used to address that uncertainty. (Decision of 12.07.2016, Case A-009-2014, *Albemarle Europe*, para. 191-193)

It was clear from the use of the words 'such as', before suggestions for extraction procedure/solvent, and the requirement to justify the method used that the contested decision did not prescribe which extraction procedure/solvent should be employed. The contested decision only made suggestions as to which extraction procedures/solvents may be appropriate. This offered guidance to the appellants as to the appropriate technique to achieve the objective of the contested decision. The contested decision was however clear that whichever procedure/solvent is employed, the appellants must demonstrate that it is sufficient to extract the non-irreversibly bound fraction from the soil matrix and that the remaining part is the irreversibly bound fraction. (Decision of 25 September 2018, Case A-008-2017, *SI Group-UK*, para. 91)

On grouping option to address request on multiple forms of a substance see *Decision of 30.06.2017, Case A-015-2015, Evonik Degussa, para. 200-202.*

Article 25(1) REACH. The protection of animal welfare is therefore an important consideration in the framework of EU legislation and the REACH Regulation in particular. Under the REACH Regulation, ECHA has a legal obligation to consider animal welfare in its decision-making. Where ECHA requires additional testing pursuant to a substance evaluation, it must ensure that vertebrate animals are used only as a last resort and its actions should demonstrably not run counter to the principles of Directive 2010/63. (Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 108; Decision of 30.06.2017, Case A-014-2015, *Grace*, para. 172-174; Decision of 30.06.2017, Case A-015-2015, *Evonik Degussa*, para. 248-250)

> ***Illustration***. The absence of analysis of alternatives was not sufficient to lead to the annulment of the contested decision, a.o. because during the present proceedings ECHA stated that there are no alternatives to the Comet assay. The BoA also rejected the appellants' plea that the Comet assay is inappropriate to examine the concern identified. The appellants had not provided evidence to support their claim that there are non-animal testing alternatives to address the mutagenicity concern identified. (Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 281)

New registrants of the substance under evaluation. An interpretation whereby registrants who submitted registration dossiers after the draft decision was notified should also be addressees of the substance evaluation decision, would lead to discrimination against these new registrants. These new registrants would not have had the same opportunity to exercise their rights of defence and to participate on an equal footing in the substance evaluation procedure. The interpretation suggested by the appellants could lead to an endless loop whereby the whole substance evaluation procedure would restart each time a new dossier is submitted during the period between the preparation of the draft decision and the adoption of the final decision. None of the above situations could have been the intention of the legislator as they would raise concerns regarding equality, due process, legal certainty and jeopardise the achievement of the primary objectives of the REACH Regulation. In addressing the contested decision only to the registrants with active registrations at the time the draft decision was notified, ECHA did not breach the principle of equal treatment. (Decision of 09.09.2015, Case A-004-2014, *Altair Chimica and Others* ['MCCP Registrants'], para. 141-142; Decision of 07.12.2016, Case A-013-2014, *BAS*F, para. 68-71)

During the period a registration is subject to the technical completeness check provided for in Article 20(2) REACH the company submitting the dossier should be considered as a '*concerned registrant*'. If the registrant subsequently fails the technical completeness check the registrant can be removed from the decision-making procedure and consultation process. (Decision of 07.12.2016, Case A-013-2014, *BASF*, para. 79-80)

Downstream users. Requests for further information under substance evaluation do not extend to downstream users in general. The request for further information may extend to concerned downstream users in certain cases, for example where the substance evaluation decision covers uses for which a downstream user report has been notified to ECHA under Article 38(1) REACH. (Decision of 30.05.2017, Case A-022-2015, *Michelin*, para. 89)

It is not the responsibility of ECHA or an evaluating Member State competent authority to seek out and identify downstream users that may be interested in a substance evaluation decision. The duty to ensure that information on uses and related risks is accurate is necessarily one that is largely incumbent on actors in the supply chains themselves. (Decision of 30.05.2017, Case A-022-2015, *Michelin*, para. 93)

Cost-sharing. The cost of testing pursuant to a substance evaluation decision must be shared by all existing and future registrants of the substance in a fair, non-discriminatory and transparent way. (Decision of 07.12.2016, Case A-013-2014, *BASF*, para. 90-94)

No obligation to wait for the review of a study. There was no requirement for ECHA to wait for the conclusions of an on-going review of an existing publication nor to require the conduct of such a review prior to requesting any tests on vertebrate animals . If the opposite was the case, the delays inherent in having to wait for previous tests on animals to be re-assessed every time a concern is identified, before conducting additional testing, would be incompatible with the primary objective of the REACH Regulation, that is to achieve a high level of protection of human health and the environment. (Decision of 30.06.2017, Case A-014-2015, *Grace*, para. 177)

No obligation to wait for a registrant to generate information to support potential adaptations. ECHA is not required to postpone its decision-making to wait for a registrant to generate information to support potential adaptations. This is especially the case where the date on which that information will become available is unknown or imprecise. There is no obligation for ECHA to wait for the Appellant to develop an adaptation which, ultimately, may not be acceptable. Waiting to request information where a potential risk has been identified would not serve the main objective of the registration and evaluation provisions in the REACH Regulation, namely the protection of human health and the environment. (Decision of 30.01.2018, Case A-005-2016, Cheminova, para. 49; Decision of 22.03.2022, Case A-003-2020, *Campine Belgium*, para. 115-116, 199, 238; Decision of 22.03.2022, Case A-004-2020, *Tribotecc Austria*, para. 115-116, 199, 238; Decision of 22.02.2022, Case A-005-2020, *S. Goldmann & Co. Germany*, para. 113-114, 206, 247)

Request for establishing a realistic, precise and reliable PNEC. The objective of the relevant information requirements of the contested decision was to obtain information on the effects of the substance in question on a greater number of species than are currently included in the sensitivity distribution ('SSD') model, thereby making the predicted no-effect concentration ('PNEC') more realistic, precise and reliable. (Decision of 06.08.2018, *SI Group and Others*, Case A-006-2016, para. 162)

> ***Illustration***. The PNEC was calculated on the basis of an SSD model. The organisms included in the SSD model, the types of endpoint and life stages tested, the way in which data are combined for individual species, and the assessment factor applied to take account of uncertainties, are all highly relevant aspects for the calculation of the PNEC. The SSD model for the substance in question had been established on the basis of a number of taxonomic groups, leading to a PNEC of 0.6 µg/l in freshwater. However, as stated in the contested decision, and not contested by the appellant, there were several studies which suggested that the margin of safety this provides for some taxonomic groups is low, and may be insufficient in some cases. Finally, it was irrelevant whether or not ECHA's guidance on registration lists an assessment factor of 5 at most, as the appellants argue. The relevant information requirements of the contested decision aimed to ensure that the PNEC, and therefore the RCR, is as realistic, precise and reliable as possible. (Decision of 06.08.2018, *SI Group UK and Others*, Case A-006-2016, para. 164-165, 167, 170)

Request for information on unreacted/degraded monomers in polymers. Article 2(9) REACH in conjunction with Article 46 REACH must be interpreted as meaning that ECHA has the power to request information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers, pursuant to the substance evaluation of a monomer. Legal certainty was not breached insofar as requests relates to the polymers that the appellants manufacture or import themselves. (Decision of 06.08.2018, *SI Group UK and Others*, Case A-006-2016, para. 85, 134-143)

Request for information to be obtained from downstream users. The principles of proportionality and legal certainty require that a substance evaluation decision cannot oblige registrants to provide information which they can neither assuredly obtain nor generate themselves. The appellants were not obliged to refuse to supply the registered monomer to their downstream users if those downstream users refuse to provide them with information on the presence of a monomer in their polymers, or do not submit to ECHA their downstream user reports containing that information. The appellants had no means, under the REACH Regulation, to oblige their downstream users to provide them with information on the presence of the monomer in their polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers. In addition, the appellants could not be required to provide worst case assumptions regarding the presence of a monomer in the polymers of their downstream users as this also depends on the requirement to obtain information from their downstream users. (Decision of 06.08.2018, *SI Group UK and Others*, Case A-006-2016, para. 102, 108-109, 114)

Decision requiring registrants to disclose to each other potentially confidential information. The requirement to test four '*forms'* of the substance in question potentially required the addressees of the contested decision to share information on their commercial products. If the appellants were concerned about sharing confidential business information, for example on the composition of their products, a third party representative could be appointed to determine the '*forms'* that should be tested. (Decision of 30.06.2017, Case A-014-2015, *Grace*, para. 164)

The contested decision obliged the appellants to submit to ECHA certain information on the registered monomer and on the polymers made from the registered monomer that they themselves manufacture or import. The contested decision gives the appellants leeway as to how to do this. For example, the appellants may submit this information individually, or they may make use of the services of a third party to gather, present and submit it. Even if the information at issue were such that its sharing could lead to an infringement of Articles 101 or 102 TFEU, the appellants can therefore comply with the requirements of both the contested decision and Articles 101 and 102 of the TFEU. (Decision of 06.08.2018, *SI Group UK and Others*, Case A-006-2016, para. 131-132)

Deadline for submitting information. The appellants had not demonstrated that the information could not be provided within the 15 months deadline provided for in the contested decision. The test house contacted by the appellants indicated that, at that time, there would be a delay of around 4 months before it could start the second species PNDT study. However, it was not clear that similar delays would apply at the time of the BoA decision or would be faced in other test houses. Second, ECHA stated at the hearing that it had also contacted test houses that indicated that around 12 months would be sufficient to perform the requested tests. Third, the requested second species PNDT study and the Comet assay could be conducted in parallel. (Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 286-290)

Substantial new information. ECHA is required to take into account all substantial new information during a substance evaluation decision-making procedure irrespective of the means chosen to bring that information to its attention, provided that such means of transmission ensure that ECHA is informed in a clear and comprehensive way. However, ECHA and the eMSCA are not required to monitor the availability of new scientific publications relevant to the substance evaluation in question. (Decision of 10.05.2021, Case A-002-2021, *Lanxess Deutschland and Schirm*, para. 65, 72)

14. REACH – RELATIONSHIP BETWEEN DOSSIER AND SUBSTANCE EVALUATION

Difference between substance and dossier evaluation. The requirement in Article 47 REACH cannot be applied to a compliance check of a registration dossier by analogy. This is due to the differences between the objectives of the substance evaluation and compliance check processes under the REACH Regulation. Whilst the compliance check of a registration dossier normally aims at verifying whether a registration dossier complies with the applicable information requirements the objective of substance evaluation is to clarify the potential risks that a substance poses to human health or the environment. (Decision of 24.03.2020, Case A-006-2018, *Emerald Kalama Chemical and Others*, para. 105; Decision of 23.09.2015, Case A-005-2014, *Akzo Nobel and Others*, para. 76)

Compliance check should normally precede substance evaluation. Whilst the REACH Regulation contains no explicit requirement that dossier evaluation should precede substance evaluation, there are a number of indications in the REACH Regulation which suggest that the normal course of action should be for ECHA to carry out a compliance check prior to the performance of a substance evaluation. Pursuing dossier evaluation prior to substance evaluation should ensure that the latter evaluation is carried out on the basis of a more 'complete' set of data. Evaluation of a 'complete' data set may allow it to be concluded, for example, that the substance does not constitute a risk and that no further data is required. … [Articles 47(1) and 42(2)] suggest that a compliance check is foreseen in some cases even before the substance is placed on the CoRAP and therefore prior to the substance evaluation process. … Pursuant to Article 41(5) REACH, ECHA was required to perform a compliance check on at least 5% of the total number of dossiers received for each tonnage band. Whilst ECHA is not therefore required to perform a compliance check on all registration dossiers, according to Article 41(5)(c) REACH one of the prioritisation criteria for selecting dossiers for a compliance check is that 'the dossier is for a substance listed in the [CoRAP] referred to in Article 44(2) REACH.' This provision again suggests that a compliance check should normally be performed by ECHA before the substance evaluation process is initiated. (Decision of 23.09.2015, Case A-005-2014, *Akzo Nobel and Others*, para. 77-81)

However, ECHA is not required to always perform a full compliance check under Article 41, concerning all information contained in a registration dossier for a substance, before performing a substance evaluation on that substance. (Decision of 22.03.2022, Case A-003-2020, *Campine Belgium*, para. 193; Decision of 22.03.2022, Case A-004-2020, *Tribotecc Austria*, para. 193; Decision of 22.02.2022, Case A-005-2020, S. *Goldmann & Co. Germany*, para. 200)

A perceived gap in the standard information requirements cannot, in itself, justify a request to fill such a data gap pursuant to substance evaluation. A data gap does not constitute on its own evidence of a potential risk for human health or the environment. In other words, ECHA's conclusion that the failure of one of the appellants to provide some of the standard information in their registration dossier could not, on its own, justify a request for that information pursuant to substance evaluation. (Decision of 23.09.2015, Case A-005-2014, *Akzo Nobel and Others*, para. 75; Decision of 12.07.2016, Case A-009-2014, *Albemarle Europe*, para. 89)

If data gaps in registration dossiers could be filled through substance evaluation and directed at several registrants of a substance, regardless of the tonnage registered and the type of registration made, with the associated consequences for cost sharing, this could undermine the balance achieved in the legislation, for example between cost and information. Filling a standard information requirement through substance evaluation could lead to significant costs for low tonnage and intermediate registrants who would not be exposed to such costs if the standard information had been provided through a registration by a higher volume registrant. ECHA should not therefore without clear justification, in effect, extend the standard information requirements. Nonetheless, the standard information requirements set out in Annexes VII to X REACH may, in certain circumstances, be requested under substance evaluation. For example, ECHA could potentially request information that is standard at the highest tonnage band for a substance that has not been registered at that tonnage band or for a substance that has been registered at the highest tonnage band but the relevant test results were not included as the information requirement was successfully waived in a registration dossier. (Decision of 23.09.2015, Case A-005-2014, *Akzo Nobel and Others*, para. 84-88)

Exception in case of concern. Standard information for a registration may be required under substance evaluation if: (a) ECHA can demonstrate that the substance concerned presents a potential risk to human health or the environment; and (b) the rights of all current registrants of the substance concerned are not prejudiced by ECHA's decision to follow the substance evaluation rather than the dossier evaluation procedure. (Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 123; Decision of 25 September 2018, Case A-007-2017, *Infineum UK*, para. 53; Decision of 25 September 2018, Case A-008-2017, *SI Group-UK*, para. 51)

ECHA must provide sufficient reasoning to justify, in light of the objectives of the REACH Regulation and the substance evaluation process, and in particular the protection of human health and the environment, requesting information that should have ordinarily been requested following a dossier evaluation procedure under substance evaluation. (Decision of 23.09.2015, Case A-005-2014, *Akzo Nobel Industrial Chemicals and Others*, para. 61; Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 134; in the latter case, the lack of justification was, however, not found to lead to the annulment of the decision based on the circumstances of the case)

> ***Illustration***. These conditions were met because (1) none of the addressees of the contested decision were required to provide information that they were not required to provide for registration purposes, (2) all the addressees were at the same tonnage band and, in the absence of individual separate adaptation, they were required to share the costs incurred in generating the information irrespective of whether the information was requested under dossier evaluation or substance evaluation, and (3) due to the concern, ECHA's evaluation of the appellants' adaptation (no trigger for PNDT 2nd species at Annex IX) would have been the same under dossier evaluation and substance evaluation. (Decision of 13.12.2017, Case A-023-2015, *Akzo Nobel Chemicals and Others*, para. 127-130)
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> ***Illustration***. The BoA found that registrants' rights may have been prejudiced by ECHA's failure to assess, at any time or through any procedure, whether there were '*serious concerns about the potential for adverse effects on fertility or development*' and therefore whether the EOGRTS requested in the contested decision was a standard information requirement under Annex IX or under Annex X REACH. Thus, it is not known which of the registrants of the substance should be required to pay a share of the costs relating to the performance of that test. (Decision of 25 September 2018, Case A-007-2017, *Infineum UK*, para. 68-69; Decision of 25 September 2018, Case A-008-2017, *SI Group-UK*, para. 66-67)
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> ***Illustration***. The substance evaluation procedure should not, ordinarily, be used in place of a compliance check to fill data gaps. However, ECHA may be able to provide sufficient reasoning to justify in certain cases, in light of the objectives of the REACH Regulation and substance evaluation and in particular the protection of human health and the environment, requesting information that should have, ordinarily, been requested following a compliance check procedure as set out in Article 41 REACH. For example, if ECHA can show that there is an immediate, relevant and real concern for human health or the environment from the use of a substance it may be appropriate to request the relevant effect data and/or information on exposure under the substance evaluation procedure rather than waiting for a compliance check to be conducted, and a decision implemented, ahead of a substance evaluation. (Decision of 23.09.2015, Case A-005-2014, *Akzo Nobel and Others*, para. 90)
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> ***Illustration.*** All the addressees of the contested decision were subject to the same information requirements for registration purposes. As a result, all information requested in the contested decision was relevant for all addressees of the contested decision and not only a certain number of them, as was the situation in *Akzo Nobel Industrial Chemicals and Others*. In addition, the concerns being investigated were typical of those effects which should be investigated pursuant to substance evaluation as the contested decision was examining environmental effects holistically through the use of modified testing requirements. (Decision of 12.07.2016, Case A-009-2014, *Albemarle Europe*, para. 92-95)

Illustration. First, non-standard information would not necessarily be requested following a compliance check of a registration dossier. Second, whilst the contested decision requests information from individual registrants, this request results from a substance evaluation procedure whereby the eMSCA and ECHA have access to a far wider pool of information on the uses of the substance than would otherwise be available during a compliance check of the individual registration dossiers. The possibility provided by the substance evaluation process to look at 'all relevant information submitted' on the substance, that is all the registration dossiers, could help in the identification of information needs on exposure from individual registrants that could be pertinent to the wider risk assessment and management of the substance. In particular, by examining all relevant information submitted on a substance it may become more apparent that further exposure information is needed than would be the case by examining a single registration dossier and the uses covered by it. Third, it would be time consuming and inefficient for ECHA to undertake compliance checks of several registration dossiers in order to adopt decisions to help clarify the potential risk identified during a substance evaluation. Moreover, such an approach would run contrary to the primary objective of the REACH Regulation which is to ensure a high level of protection of human health and the environment. (Decision of 27.10.2015, Case A-006-2014, *International Flavors & Fragrances*, para. 61)

Illustration. It was uncontested that the information requested in the contested decision goes beyond the standard information requirements of the testing Annexes. ECHA could therefore only request this information under substance evaluation. (Decision of 29.01.2020, Case A-008-2018, *Taminco and Performance Additives Italy,* para. 43; Decision of 22.03.2022, Case A-003-2020, *Campine Belgium*, para. 192-194; Decision of 22.03.2022, Case A-004-2020, *Tribotecc Austria*, para. 192-194; Decision of 22.02.2022, Case A-005-2020*, S. Goldmann & Co. Germany*, para. 201-203)

Interface with the dossier evaluation follow-up procedure. In the circumstances of this case, ECHA was not required to follow the procedure set out in Article 42(1) REACH in order to request a PNDT study in a second species. As the testing proposal process was considered to be complete it was not necessary for ECHA to draft a decision in accordance with Article 40 REACH and in turn go through the decision-making procedure foreseen in Articles 50 and 51 REACH. If ECHA had concluded that the information provided by the appellants did not satisfy the information requested in the testing proposal decision of 20 December 2012, ECHA may, depending on the information provided, have been required to draft a new decision in accordance with Article 42(1) REACH, following the procedure set out in Articles 50 and 51 REACH. (Decision of 13.12.2017, Case A-023-2015, Akzo *Nobel Chemicals and Others*, para. 119)

15. BPR – REVIEW PROGRAMME

Notification of food and feed used as attractants. In applying the eligibility criteria laid down in Article 15 of the new Review Programme Regulation in the present case, ECHA should have first assessed whether the peanut butter bait is a biocidal product within the meaning of Article 3(1)(a) BPR. In the affirmative, ECHA should have next assessed whether it falls within the scope of the BPR. In particular, this would have required ECHA to examine whether the peanut butter bait is covered by the exemption for food and feed used as repellents or attractants laid down in Article 2(5)(a) BPR. If the peanut butter bait was found to fall within the scope of the BPR, ECHA should have next assessed whether it consists of, contains or generates an existing active substance. In the affirmative, ECHA should have assessed whether the active substance is already approved, or included in the Review Programme. (Decision of 04.04.2019, Case A-013-2017, *SwissInno Solutions (Peanut butter)*, para. 51; Decision of 04.04.2019, Case A-014-2017, *SwissInno Solutions (Brandy)*, para. 51)

16. BPR – TECHNICAL EQUIVALENCE

Requests for further information. Under Article 54(1) and (2) BPR, it is for the person seeking to establish technical equivalence – the applicant – to submit to ECHA an application containing all the information needed by ECHA to carry out its assessment of technical equivalence. If ECHA considers, under Article 54(5) BPR, that the information provided in an application for technical equivalence submitted under Article 54(1) BPR is insufficient to carry out the assessment of technical equivalence, ECHA must not only request additional information but also specify clearly and comprehensively what additional information is needed. (Decision of 24.11.2020, Case A-004-2019, *ARKEMA*, para. 48-54)

17. BPR – DATA-SHARING

Inquiry. According to the first subparagraph of Article 62(2) BPR, a prospective applicant must inquire with ECHA whether the studies they intend to perform using vertebrate animals have already been submitted to ECHA or to the competent authority of a Member State. If the studies have already been submitted to ECHA or the competent authority of a Member State, ECHA provides the prospective applicant with the name and contact details of the data submitter and the data owner. However, after a prospective applicant has made this inquiry once it has the necessary information to contact the data submitter and the data owner. Therefore, there is no need for the prospective applicant to repeat the inquiry if it needs to submit a new data-sharing dispute with ECHA concerning the same studies. (Decision of 10.03.2020, Case A-007-2018, *Sumitomo Chemical*, para. 62)

Time-limit for the adoption of the decision. The 60-day time-limit for ECHA to take a decision under Article 63(3) BPR starts running with the filing of a data sharing dispute by a prospective applicant. ECHA should adopt a decision on an application for permission to refer within 60 days of the filing of the dispute. (Decision of 10.03.2020, Case A-007-2018, *Sumitomo Chemical*, para. 82, 83)

However, the BPR does not provide for specific consequences if ECHA does not respect this time-limit. Therefore, this breach cannot lead to the annulment of the contested decision. However, a breach of the time-limit can potentially give rise to a declaration by the EU courts that ECHA failed to act (Article 265 TFEU) or an award of damages (Article 340 TFEU). (Decision of 10.03.2020, Case A-007-2018, *Sumitomo Chemical*, para. 86, 87)

Conditions for granting permission to refer. ECHA is required to examine the efforts made leading up to the moment of the submission of the data sharing dispute. It is not required, however, to assess events that may occur after the data sharing dispute was submitted. (Decision of 04.04.2017, Case A-001-2016, *Troy Chemical*, para. 126)

It is only in the event that the conditions to be granted permission to refer were not met on the day the contested decision was adopted that the BoA may annul the decision or exercise any power which lies within the competence of ECHA. (Decision of 10.03.2020, Case A-007-2018, *Sumitomo Chemical*, para. 92)

ECHA should not examine whether the actual and precise cost of a letter of access is reasonable or justified. The BoA considers that ECHA is entitled however to make an assessment of whether each of the parties to the data sharing dispute made, pursuant to Article 30(1) REACH, '*… every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way*'. Furthermore, the BoA observes that this requirement should be read as a whole. In other words, the test for ECHA to apply is whether every effort was made bearing in mind the need for the cost sharing to be determined in a fair, transparent and non-discriminatory way. The BoA also highlights that ECHA's analysis of a data sharing dispute is case-specific and context driven. (Decision of 04.04.2017, Case A-001-2016, *Troy Chemical*, para. 110-112)

Cost calculation method, value of studies. ECHA's assessment of whether every effort has been made should consider the negotiations as a whole and the actions of the parties throughout those negotiations. In the negotiations, the intervener and the appellant disagreed not only on the value of the studies, which was the starting point of the negotiations, but also on the cost calculation method used by the intervener in its different offers. By focusing in the contested decision solely on the intervener's proposal to get the value of the studies assessed by a third party, ECHA failed to consider that the parties' deadlock concerning the discussion on the cost calculation method also played a role in the negotiations. (Decision 29.05.2018, Case A-007-2016, *Sharda Europe,* para. 59-64-67)

The task of ECHA in a data sharing dispute is to examine the efforts made by each party to reach an agreement during data sharing negotiations. The BoA considers the balance of efforts

between the parties, and whether this balance is correctly reflected in the contested decision. (Decision of 23.08.2016, A-005-2015, *Thor*, para. 65)

An assessment of the fair, transparent and non-discriminatory nature of data sharing negotiations cannot be completely separated from the assessment of the negotiations on the cost sharing. Therefore, whilst ECHA cannot examine whether the cost calculation method is in itself fair, transparent and non-discriminatory, the BoA considers that ECHA should consider whether the parties, when negotiating a calculation method did so in good faith, or in other words with a real intention to find an agreement. This assessment will necessarily include considerations on cost sharing but should be limited to analysing the parties' behaviour rather than the actual amounts involved. For example, a data owner's behaviour must not be such as to create a barrier for a prospective applicant to enter the biocidal products market. Equally, the condition of paying a share of the costs cannot be construed as a simple formal requirement whereby ECHA would automatically grant access to studies by virtue of proof of any kind of payment once it has established that every effort has been made in the negotiations. (Decision of 04.04.2017, Case A-001-2016, *Troy Chemical*, para. 112)

Payment of a share of the cost. The context and the objectives of the BPR do not support the appellant's interpretation of Article 63(3) REACH, which would require that the condition of a payment of a share of the costs incurred should have been made before the data sharing dispute was lodged by the intervener, or before ECHA has assessed whether every effort has been made. (Decision of 04.04.2017, Case A-001-2016, *Troy Chemical*, para. 69 and 76)

The share of the cost paid must not be manifestly unreasonable. However, ECHA does not have the competence to rule whether the share of costs paid by a prospective applicant is not only not manifestly unreasonable, but also proportionate. The appellants can bring such a matter to a national court, unless the parties are able to find an agreement. (Decision of 10.03.2020, Case A-007-2018, *Sumitomo Chemical*, para. 97, 98)

Contractual agreements. Neither ECHA nor the BoA have the power to declare null and void a contractual agreement between private parties to a data and cost-sharing dispute. Similarly, neither ECHA nor the BoA can disregard – as if it had been declared null and void by a competent body – a clause in a contractual agreement between private parties to a data and cost-sharing dispute. (Decision of 03.11.2020, Case A-009-2019, *Solvay Solutions*, para. 59)

Parties are free to make the data sharing agreement conditional upon the performance of a technical equivalence assessment, even though such assessment might not be required by law. ECHA committed an error in finding that the appellant did not make every effort when making the data sharing agreement conditional upon the performance of a technical equivalence assessment when the data claimant had explicitly agreed to such a condition. (Decision of 23.08.2016, A-005-2015, *Thor*, para. 74)

The appellant and the intervener have the contractual freedom to insert a clause relating to chemical similarity in a secrecy agreement. Although establishing chemical similarity is not a requirement for applications under Article 95 REACH, the appellant and the intervener can decide nevertheless to be bound by a contractual agreement according to which chemical similarity is a pre-requisite to the continuation of negotiations and to data sharing. (Decision 07.03.2018, Case A-014-2016, *Solvay Solutions UK*, para 54-55)

As stated above the appellant and the intervener have the contractual freedom to insert a clause relating to chemical similarity in a secrecy agreement. This means that if such a clause is triggered, the appellant and the intervener must adhere to it unless they mutually and explicitly agree to change or ignore it. The assessment of the appellant's and the intervener's conduct in the negotiations must be examined in this context. (Decision 07.03.2018, Case A-014-2016, *Solvay Solutions UK*, para 61)

Accepting all terms and conditions. A prospective applicant can be found to have made every effort to reach an agreement even if it does not accept the terms and conditions proposed by a data owner. However, where a prospective applicant has accepted all the terms and conditions proposed by the 'data owner', it has made every effort. (Decision of 10.03.2020, Case A-007-2018, *Sumitomo Chemical*, para. 93-95)

Arbitration. The word '*may*' used in Article 63(1) BPR indicates that submission of the matter to an arbitration body is only a possibility and not an obligation. It is only one means to find a solution to a data sharing negotiation. Using an arbitration body depends on the consent of both of the parties to a data sharing negotiation. A proposal to refer a data sharing negotiation to a third party cannot be construed as a substitute for the obligation to make every effort to reach a data sharing agreement. (Decision 29.05.2018, Case A-007-2016, *Sharda Europe*, para 73-74)

Proof of payment. In order to constitute 'a share of the costs incurred' within the meaning of the first sentence of the second subparagraph of Article 63(3) of the BPR, the amount paid by a prospective applicant must not be manifestly unreasonable having regard to the circumstances of the case. (Decision of 03.11.2020, Case A-009-2019, *Solvay Solutions*, para. 70-74)

No exclusion of data-sharing in case of differences in hazard profile. Any possible differences in the hazard profile of an active substance from the two sources of two review programme participants – if such differences exist – will be taken into account during the course of the procedure for the approval of the active substance under Chapter II BPR. Therefore, a plea that ECHA breaches the precautionary principle because of possible differences in the hazard profile of the active substance from the source of the prospective applicant must be rejected – at least as long as the parties had not agreed contractually that they would only share data if the two sources are similar. (Decision of 10.03.2020, Case A-007-2018, *Sumitomo Chemical*, para. 104-106)