Reports of Cases

Case T-610/17

ICL-IP Terneuzen, BV
and
ICL Europe Coöperatief UA
v
European Commission

Judgment of the General Court (Fifth Chamber), 20 September 2019

(REACH — Substances subject to authorisation — Inclusion of 1-bromopropane (nPB) in Annex XIV of Regulation (EC) No 1907/2006 — Quantity — Registration dossier — Data — Grouping of substances — Principle of sound administration — Right to do business and to trade freely — Obligation to state reasons — Legitimate expectations — Proportionality — Equal treatment)

1. *Approximation of laws — Registration, evaluation and authorisation of chemicals — The REACH Regulation — Substances of very high concern — Procedure for inclusion in Annex XIV — Discretion of the EU institutions — Scope — Judicial review — Limits*
(European Parliament and Council Regulation No 1907/2006)

(see paragraphs 75, 158)

2. *Approximation of laws — Registration, evaluation and authorisation of chemicals — The REACH Regulation — Obligation to register with the European Chemicals Agency (ECHA) — Information obligation requiring the registrant of a substance to update the data set out in his registration dossier — Scope*
(European Parliament and Council Regulation No 1907/2006, recitals 14, 17, 19, 21, 27 and 46, and Arts 1(3), second sentence, and 22 (1)(c))

(see paragraphs 76-83, 87-92, 112)

3. *Approximation of laws — Registration, evaluation and authorisation of chemicals — The REACH Regulation — Substances of very high concern — Procedure for inclusion in Annex XIV — Grouping of substances — Obligation of the Commission to assess whether suitable alternative substances or technologies are available, taking all relevant aspects into account — None*
(European Parliament and Council Regulation No 1907/2006, Art. 60(4))

(see paragraphs 166, 167)

4. *Approximation of laws — Registration, evaluation and authorisation of chemicals — The REACH Regulation — Substances of very high concern — Procedure for inclusion in Annex XIV — Prioritisation by European Chemicals Agency (ECHA) of candidate list substances — Non-exhaustive list of criteria — Commission's margin of discretion — Consideration of a grouping criterion for two substances — Whether permissible*
(European Parliament and Council Regulation No 1907/2006, Art. 58(3))

(see paragraphs 186-188)

Résumé

On 20 September 2019, in the judgment in *ICL IP Terneuzen and ICL Europe Coöperatief UA* v *Commission* (T-610/17), the Court dismissed an action to set aside, in part, Commission Regulation 2017/999.[1] In particular, it ruled on the scope of the information obligation which requires the registrant of a substance to update the data set out in his registration dossier, in accordance with Article 22(1)(c) of Regulation No 1907/2006.[2]

The applicant companies are the registrants of the substance nPB.[3] In their registration dossiers, the applicants had not only provided data on the total quantity of the substance in question but had also provided additional data on the quantity of that substance falling within the scope of authorisation. The quantity of a substance that falls within the scope of authorisation is less than its total quantity, since the quantity relating to intermediate uses is excluded. This is an element the Commission takes into account when deciding which candidate substance to include in Annex XIV of Regulation (EC) No 1907/2006, which lists the substances subject to authorisation. This regulation does not explicitly impose an obligation to update these additional data when the quantities falling within the scope of authorisation are modified and could affect the prioritisation of the substance as regards its inclusion in Annex XIV of Regulation No 1907/2006.

On 13 June 2017, on the basis of a favourable opinion from the regulatory committee and on the recommendation of the European Chemicals Agency (ECHA), the Commission adopted Regulation 2017/999, in terms of which nPB was included in Annex XIV to Regulation No 1907/2006. It considered that nPB met the criteria for classification of a substance as toxic for reproduction and, therefore, satisfied the conditions for inclusion in that annex.

The registrants then lodged an action for annulment of Regulation 2017/999, arguing that the inclusion of that substance in Annex XIV was premature, due in particular to the Commission's manifest errors of assessment. The latter had, indeed, erred in its use of the data from the registration dossier for the substance, which covered all uses of the substance, including uses not normally falling within the scope of authorisation, and had not taken sufficient account of data provided in the context of the public consultation and subsequently.

First, after having noted inconsistencies between data relating to quantities for each use of the substance in question, set out in paragraph 3.5 of the registration dossier, and those relating to

[1] Commission Regulation (EU) 2017/999 of 13 June 2017 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation Authorisation and Restriction of Chemicals (REACH) (OJ 2017 L 150, p. 7).

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1).

[3] 1-bromopropane (n-propyle bromide, nPB).

the total quantity of the substance, set out in paragraph 3.2 of the same dossier, the Court decided, having regard to the precautionary principle, as mentioned in Article 1(3), second sentence, of Regulation No 1907/2006, that the Commission cannot be criticised for relying on the initial data, which showed a higher quantity of the said substance to be falling within the scope of authorisation.

Secondly, the Court noted that Article 22(1)(c) of the regulation, which imposes a duty on registrants, in the event of changes in certain quantities and on their own initiative and without undue delay, to update their registration dossiers with relevant new information and to submit them to ECHA, applies to the overall tonnage ranges set out in Regulation No 1907/2006, which must be stated when a substance is being registered, and not to that portion of the quantity which falls within the scope of authorisation.

However, having regard to the important role of the data in the dossier, in that they constitute the principal source of information for the prioritisation exercise carried out by ECHA, and having regard to the registrant's responsibilities regarding the data, the Court decided that it is the registrant's responsibility to update the data in due time, if those data are relevant to the purposes of the procedures set out in Regulation No 1907/2006, even if they are not data such as are referred to in Article 22(1)(c) of that regulation, namely those relating to quantities relating to the various uses of a substance.