COURT OF JUSTICE
OF THE EUROPEAN UNION

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MONTHLY CASE-LAW DIGEST
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I. PROTECTION OF PERSONAL DATA

Judgment of the Court of Justice (First Chamber) of 26 October 2023, FT (Copies of medical records), C-307/22

Link to the full text of the judgment

Reference for a preliminary ruling – Processing of personal data – Regulation (EU) 2016/679 – Articles 12, 15 and 23 – Data subject's right of access to his or her data undergoing processing – Right to obtain a first copy of those data free of charge – Processing of a patient's data by his or her medical practitioner – Medical records – Reasons for the request for access – Use of data for the purpose of triggering the liability of the person providing treatment – Concept of 'copy'

DW requested that FT, his dentist, provide him with a first copy of his medical records free of charge. He made that request with a view to triggering FT's liability for errors allegedly made by her in providing him with dental care.

Relying on German law pursuant to which the patient may obtain a copy of his or her medical records on condition that he or she reimburse the person providing treatment for the costs resulting therefrom, [1] FT refused to provide DW with such a copy, following which DW brought an action. Both the court of first instance and the court hearing the appeal upheld DW's request to be provided with a first copy of his medical records free of charge.

Hearing an appeal on a point of law (*Revision*) brought by FT, the Bundesgerichtshof (Federal Court of Justice, Germany) has put questions to the Court of Justice concerning the interpretation of the provisions of the GDPR which refer to the rules governing the exercise of the data subject's right of access to his or her data, as well as the restrictions of the scope of that right. [2]

By its judgment, the Court concludes, first of all, that, where the data subject so requests, the controller is obliged to provide him or her with a first copy of his or her personal data, free of charge, for purposes other than becoming aware of the processing of those data and verifying the lawfulness of that processing, which are explicitly referred to in the preamble to the GDPR. Next, it rules on the parameters of the option for the Member States to restrict, in the name of the economic interests of the controller, the right to obtain a copy of the data by requiring the data subject to pay fees incurred by that controller in that regard. Lastly, it examines the need to provide the data subject, in certain cases, with a full copy of the data in his or her medical records.

Findings of the Court

In the first place, as regards the question whether the controller is also under an obligation to provide the data subject with a first copy of his or her data free of charge with a view to pursuing purposes other than those explicitly referred to in the preamble to the GDPR, the Court recalls that the first sentence of Article 15(3) of that regulation confers on the data subject the right to obtain a faithful reproduction of his or her personal data, understood in a broad sense, that are subject to operations that can be classified as 'processing carried out by the controller'. [3] In addition, it follows from a

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1 Second sentence of subparagraph 2 of Paragraph 630g of the Bürgerliches Gesetzbuch (German Civil Code).

2 More specifically, Article 12(5), Article 15(1) and (3), and Article 23(1)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ 2016 L 119, p. 1, and corrigendum OJ 2018 L 127, p. 2) ('the GDPR').

3 Judgment of 4 May 2023, Österreichische Datenschutzbehörde and CRIF (C-487/21, EU:C:2023:369, paragraph 28).

combined reading of the relevant provisions of the GDPR [4] that (i) the data subject has the right to obtain a first copy, free of charge, of his or her personal data undergoing processing and (ii) the controller is given the option, under certain conditions, to charge a reasonable fee taking administrative costs into account or to refuse to act on a request if it is manifestly unfounded or excessive.

However, none of those provisions makes the provision, free of charge, of a first copy of personal data conditional upon a data subject putting forward reasons to justify his or her request. Accordingly, the reasons for requests set out explicitly in the preamble to the GDPR [5] cannot restrict the scope of those provisions. Thus, the right to access data relating to health [6] cannot be restricted, either by refusing to grant access or by requiring the payment of consideration, to one of those reasons – a finding which also applies as regards the right to obtain a first copy free of charge.

In addition, the principle that the first copy of the data should be free of charge and the lack of a need to rely on a specific reason to justify the request for access necessarily contribute to facilitating the exercise, by the data subject, of the rights conferred on him or her by the GDPR. Consequently, given the importance which the regulation ascribes to the right to access personal data for achieving the objectives pursued by that regulation, the exercise of that right cannot be made subject to conditions which have not been expressly laid down by the EU legislature.

In the second place, the Court rules that a Member State is not entitled to adopt a piece of national legislation which, in order to protect the economic interests of the controller, makes the data subject bear the costs of a first copy of his or her personal data.

It is true that, under the GDPR, the right of the data subject to obtain a first copy, free of charge, of his or her personal data is not absolute and, under certain conditions, the protection of the rights and freedoms of others could justify a restriction of that right. [7] However, in the present case, in so far as the objective of the piece of national legislation is to protect the economic interests of persons providing treatment by preventing needless requests for copies, such considerations cannot be included in such rights and freedoms.

Indeed, that piece of legislation deters not only needless requests, but also requests seeking to obtain, for a legitimate reason, a first copy, free of charge, of processed personal data. Consequently, it is necessarily in breach of the principle that the first copy should be free of charge and thereby undermines the effectiveness of the data subject's right of access to his or her data, provided for by the GDPR, as well as, as a result, the protection guaranteed therein.

Furthermore, the Court emphasises that the economic interests of controllers were taken into account under the GDPR, which defines the circumstances in which the controller may charge a fee connected with the provision of a copy of personal data.

In the third and last place, the Court considers that, in doctor-patient relationships, the right to obtain a copy of personal data means giving the data subject a faithful and intelligible reproduction of all those data. That right entails the right to obtain a full copy of the documents included in his or her medical records if this is essential in order to enable the data subject to verify how accurate and exhaustive his or her data are, as well as to ensure they are intelligible.

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4 Article 12(5) and Article 15(1) and (3) of the GDPR.

5 The first sentence of recital 63 of the GDPR states that 'a data subject should have the right of access to personal data which have been collected concerning him or her, and to exercise that right easily and at reasonable intervals, in order to be aware of, and verify, the lawfulness of the processing'.

6 Guaranteed in Article 15(1) of the GDPR.

7 Pursuant to Article 23(1)(i) of the GDPR.

In that regard, it notes that, as regards personal data relating to health, the GDPR specifies that the right of access of data subjects includes 'the data in their medical records containing information such as diagnoses, examination results, assessments by treating physicians and any treatment or interventions provided'. [8] It is because of the sensitive nature of those data that the EU legislature thus highlighted the importance of ensuring that natural persons are given access to the data contained in their medical records as fully and precisely as possible, but also in a form which is intelligible.

Regarding examination results, assessments by treating physicians and treatments or interventions provided to a patient, which, as a general rule, involve a large amount of technical data, or even images, the provision of a simple summary or a compilation of those data by the medical practitioner, in order to present them in an aggregated form, could create the risk of some relevant data being omitted or incorrectly reproduced, or, in any event, of it being made harder for the patient to verify how accurate and exhaustive those data are and to understand those data.

II. FREEDOM OF MOVEMENT: FREE MOVEMENT OF CAPITAL

Judgment of the Court of Justice (First Chamber) of 12 October 2023, BA (Inheritance – Public housing policy in the European Union), C-670/21

Link to the full text of the judgment

Reference for a preliminary ruling – Taxation – Free movement of capital – Articles 63 to 65 TFEU – Inheritance tax – Movement of capital between Member States and third countries – Immovable property located in a third country – More favourable tax treatment for immovable property located in a Member State or in a State which is party to the Agreement on the European Economic Area – Restriction – Justification – Housing policy – Effectiveness of fiscal supervision

A, a German resident, who died in 2016, bequeathed in 2013 to his son, BA, also a German resident, a share of an immovable property located in Canada let for residential purposes.

In July 2017, the competent tax office determined the amount of inheritance tax payable by BA in Germany. For the purpose of calculating that tax, that immovable property was assessed at its full market value. In March 2018, BA sought to amend the amount of that tax, so that that property would be taxed at 90% of its market value, as provided for in the German law on inheritance and gift tax. Observing that that law requires, in order for that immovable property to benefit from that tax advantage, that that property be located in Germany, another Member State or a State which is party to the Agreement on the European Economic Area, [9] BA claimed that that law infringed the free movement of capital between Member States and third countries enshrined in Article 63 TFEU. Taking the view, however, that such a difference in treatment between immovable property located in one of those three types of country and property of the same nature located in a non-Member State other than a State which is party to the EEA Agreement complies with that provision, the Tax Office first rejected BA's request for amendment and then the objection which he had lodged.

8 Recital 63 of the GDPR.

9 Agreement on the European Economic Area of 2 May 1992 (OJ 1994 L 1, p. 3; 'the EEA Agreement').

Seised of an action by BA, the referring court asks the Court of Justice whether national legislation which excludes from the benefit of a tax advantage a property let for residential purposes in Canada is compatible with Article 63 TFEU. If such legislation constitutes a restriction on the free movement of capital, that court asks whether that restriction can be justified under Article 65 TFEU [10] or by an overriding reason in the public interest.

By its judgment, the Court holds that Articles 63 to 65 TFEU preclude national legislation which provides that, for the purposes of calculating inheritance tax, developed immovable property forming part of personal assets which is located in a non-Member State other than a State which is party to the EEA Agreement and is let for residential purposes is assessed at its full market value, whereas property of the same nature which is located within the national territory, another Member State or a State which is party to the EEA Agreement is assessed, for the purposes of that calculation, at 90% of its market value.

Findings of the Court

The Court finds, in the first place, that the legislation at issue, which makes entitlement to the tax advantage dependent on the location of the assets contained in the inheritance, results in immovable property situated in a non-Member State other than a State which is party to the EEA Agreement being subject to a heavier tax burden than that situated within the national territory, thus reducing the value of that inheritance and being liable to deter a natural person resident in Germany from investing in an immovable property let for residential purposes in such a non-Member State or from keeping any such property of which he or she is the proprietor. Such legislation therefore constitutes a restriction on the movement of capital for the purposes of Article 63(1) TFEU.

Examining, in the second place, whether that restriction may be justified under Article 65 TFEU, the Court notes, first of all, that the calculation of inheritance tax is, under the national legislation, directly linked to the market value of the assets included in the estate. Consequently, there is objectively no difference in situation capable of justifying unequal tax treatment so far as concerns the level of inheritance tax payable in relation to, respectively, an immovable property located in Germany, another Member State or a State which is party to the EEA Agreement and an immovable property located in a non-Member State other than States which are party to the EEA Agreement. In those circumstances, it would deprive Article 63(1) TFEU of all meaning if it were accepted that situations are not comparable solely because the immovable property in question is situated in a non-Member State other than a State which is party to the EEA Agreement, when that provision specifically prohibits restrictions on cross-border movements of capital.

Taking the view, therefore, that the difference in treatment at issue concerns situations that are objectively comparable, the Court then examines whether the different treatment of those situations can be justified by an overriding reason in the public interest.

In that regard, it recalls, first, that requirements related to public housing policy in a Member State and to the financing of that policy can, in principle, constitute overriding reasons in the public interest. Similarly, since the European Union has an economic and a social purpose, the rights under the provisions of the FEU Treaty on the freedoms of movement must be balanced against the objectives pursued by social policy, which includes proper social protection. As regards the EEA Agreement, it is

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10 According to that provision:

'1. The provisions of Article 63 shall be without prejudice to the right of Member States:

(a) to apply the relevant provisions of their tax law which distinguish between taxpayers who are not in the same situation with regard to their place of residence or with regard to the place where their capital is invested;

(b) to take all requisite measures to prevent infringements of national law and regulations, in particular in the field of taxation and the prudential supervision of financial institutions, or to lay down procedures for the declaration of capital movements for purposes of administrative or statistical information, or to take measures which are justified on grounds of public policy or public security.

2. The provisions of this Chapter shall be without prejudice to the applicability of restrictions on the right of establishment which are compatible with the Treaties. …'

in the light of the privileged relationship between the European Union and the European Free Trade Association (EFTA) States that one of its main objectives, namely extending to the EFTA States the internal market established within the territory of the European Union, must be understood. Thus, an objective relating to social policy, such as the promotion and provision of affordable rented accommodation in Member States and States which are party to the EEA Agreement, may, in principle, constitute an overriding reason in the public interest capable of justifying restrictions on the free movement of capital. However, it is not apparent that legislation such as that at issue is suitable for securing, in a consistent and systematic manner, the attainment of that objective. In particular, that legislation, which applies generally, does not focus on places where the shortage of affordable rented accommodation is particularly acute, such as in large German cities. Moreover, all categories of immovable property let for residential purposes, from the most basic to the most luxurious, may be valued at 90% of their market value for the purposes of calculating inheritance tax. In addition, it is not apparent that that legislation requires heirs to retain their housing for a certain period and to use it for rental purposes, so that they may, after obtaining the tax advantage at issue, sell that housing or use it as a second home. Consequently, that tax advantage cannot be regarded as justified by the objective of promoting and providing affordable rented accommodation in Member States and States which are party to the EEA Agreement.

Second, the Court holds that the overriding reason in the public interest relating to the need to guarantee the effectiveness of fiscal supervision cannot justify the restriction on the free movement of capital brought about by the national legislation at issue. After recalling the relevant provisions of the Tax Agreement between Germany and Canada, [11] the Court finds that the German authorities are in a position to ask the competent Canadian authorities for the information necessary to verify that the conditions laid down by the national legislation at issue are satisfied in order to grant the tax advantage referred to above when the immovable property is located in Canada.

III. COMPETITION

1. AGREEMENTS, DECISIONS AND CONCERTED PRACTICES (ARTICLE 101 TFEU)

Judgment of the General Court (Third Chamber, Extended Composition) of 18 October 2023, Clariant and Clariant International v Commission, T-590/20

Link to the full text of the judgment

Competition – Agreements, decisions and concerted practices – Ethylene market – Decision finding an infringement of Article 101 TFEU – Coordination on a purchase price element – Settlement procedure – Fine – Adjustment of the basic amount of the fine – Point 37 of the Guidelines on the method of setting fines – Repeated infringement – Point 28 of the Guidelines on the method of setting fines – Unlimited jurisdiction – Counterclaim for increase of the amount of the fine

11 Agreement between the Federal Republic of Germany and Canada for the Avoidance of Double Taxation with respect to Taxes on Income and certain other Taxes, the prevention of Fiscal Evasion and the Assistance in Tax Matters, concluded in Berlin on 19 April 2001 (BGBl. 2002 II, p. 670).

By decision of 14 July 2020 [12] ('the contested decision'), the European Commission found that four undertakings had infringed Article 101 TFEU by participating, during the period from 26 December 2011 to 29 March 2017, in a single and continuous infringement consisting of exchanging sensitive commercial and pricing-related information and of fixing a price element relating to purchases of ethylene, in Belgium, Germany, France and the Netherlands.

The four undertakings sanctioned under that decision include Clariant International AG, which accepted unreservedly its liability for its direct participation in the infringement committed in the relevant period, and Clariant AG, which accepted unreservedly its 'joint and several liability' in its capacity as parent company of Clariant International AG.

For the purposes of calculating the fine imposed jointly and severally on those two undertakings, the Commission first determined the basic amount, using the figures for the value of purchases of ethylene acquired in the period covering the last full year of participation in the infringement, which was 2016.

Second, the Commission made some adjustments to the basic amount. First, it applied a 50% increase to the basic amount of the fine due to the aggravating circumstance that it was a repeat infringement, pursuant to point 28 of the Guidelines on the method of setting fines. [13] Second, it applied a 10% increase to the basic amount in order to take into account the particular features of the case and the need to achieve sufficient deterrence, pursuant to point 37 of those same guidelines.

Third and lastly, after having made sure that the fine did not exceed 10% of the two undertakings' total turnover in 2019, the Commission granted them a reduction of 30% of the amount of the fine by way of leniency pursuant to the 2006 Leniency Notice, [14] as well as a 10% reduction for their cooperation in the settlement procedure.

Clariant AG and Clariant International AG brought an action for partial annulment of the contested decision as regards the amount of the fine imposed and, in the alternative, a reduction of that amount. They also seek dismissal of the Commission's counterclaim for an increase in the amount of the fine, to be achieved through a withdrawal of the 10% reduction granted for their cooperation in the settlement procedure.

The General Court rejects the action in its entirety and also the Commission's counterclaim. In its judgment, it addresses inter alia the question of the well-foundedness and statement of reasons for the application of an increase applied to the basic amount of the fine pursuant to point 37 of the Guidelines on the method of setting fines, on the ground that the cartel was a purchase cartel. Moreover, in the exercise of its unlimited jurisdiction, it rules on the Commission's counterclaim, seeking withdrawal of the 10% reduction granted to the applicants for their cooperation in the settlement procedure on the ground that, by the present action, they were challenging facts recognised and accepted by them for the purposes of the settlement procedure.

Findings of the Court

In the first place, the Court rejects the plea alleging that the Commission was wrong to increase the basic amount of the fine pursuant to point 37 of the Guidelines on the method of setting fines, referring to the need to take into account both the particular features of a given case and the need to achieve sufficient deterrent effect.

In the present case, the Court observes, first of all, that, given that the infringement concerned a purchase cartel and not all the parties were present on the same downstream markets, the

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12 Commission Decision C(2020) 4817 final, of 14 July 2020, relating to a proceeding under Article 101 TFEU (AT.40410 – Ethylene).

13 Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation No 1/2003 (OJ 2006 C 210, p. 2).

14 Commission notice on immunity from fines and reduction of fines in cartel cases (OJ 2006 C 298, p. 17).

Commission calculated the basic amount of the fine using the purchase value rather than the value of sales of downstream products.

Next, it finds that, in applying a 10% increase to that basic amount pursuant to point 37 of the Guidelines on the method of setting fines, the Commission duly exercised its discretion and made no manifest error of assessment. The Commission took account of the particular features of the case, namely the fact that the cartel in question was a purchase cartel and that the value of purchases, taken into account in lieu and stead of the value of sales, was not in itself liable to constitute a suitable proxy to reflect the economic importance of the infringement. It also took account of the need to achieve a deterrent effect of the fine in finding that, if the general method provided for by the Guidelines on the method of setting fines was being applied without the slightest adjustment, the deterrent effect would not be assured. The Commission was not, however, required to take account of the effects of the infringing conduct on the market, since a fine increase pursuant to point 37 of the Guidelines on the method of setting fines is not conditional on prior proof being made out of such effects.

Lastly, the Court considers that the Commission provided a statement of the reasons that led it to find that the particular features of the case and the need to achieve a deterrent effect with the fine justified departing from the general method and increasing the basic amount and that it duly explained the factors it took into consideration for determining that a 10% increase applied to the basic amount of the fine was appropriate. In that regard, given that the Commission is not required to state the figures relating to each step in the calculation method, it was not required to provide any additional explanations about the specific increase chosen.

In the second place, the Court dismisses the Commission's counterclaim. It finds that, in the settlement procedure, in return for a 10% reduction of the amount of the fine imposed on them under the standard procedure, the parties to the settlement procedure must acknowledge, inter alia, their liability for the infringement and provide an indication of the maximum amount of the fine they foresee to be imposed by the Commission and which they would accept. The Court nevertheless observes that the parties to the settlement procedure are not required under the settlement notice [15] to accept the final amount of the fine and all of its parameters in order to enter into settlement discussions.

Thus, the fact that Clariant AG and Clariant International AG accepted a maximum amount of the fine in their settlement submission is not the same as accepting the exact final amount of the fine and the method of its calculation, including the adjustments made under points 28 and 37 of the Guidelines on the method of setting fines. Moreover, the fine increases applied pursuant to points 28 and 37 of the Guidelines on the method of setting fines had not been expressly acknowledged by those undertakings in their settlement submission and had not been the subject of a common understanding with the Commission at the time of the procedure. It follows that the Commission could not assume that the applicants would no longer question the fine increases applied pursuant to points 28 and 37 of the Guidelines on the method of setting fines in the context of an action.

Accordingly, given that, by the present action, those undertakings are challenging the amount of the fine imposed on them by arguing that the application of those points was incorrect, the Commission has not succeeded in demonstrating that it is justified not to grant a 10% reduction to compensate them for their cooperation during the administrative procedure.

In the light of the foregoing, the Court dismisses the action in its entirety and also the Commission's counterclaim.

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15 Commission Notice on the conduct of settlement procedures in view of the adoption of Decisions pursuant to Articles 7 and 23 of Council Regulation (EC) No 1/2003 in cartel cases (OJ 2008 C 167, p. 1).

Judgment of the General Court (Third Chamber, Extended Composition) of 18 October 2023, Teva Pharmaceutical Industries and Cephalon v Commission, T-74/21

Link to the full text of the judgment

Competition – Agreements, decisions and concerted practices – Modafinil market – Decision finding an infringement of Article 101 TFEU – Patent dispute settlement agreement – Restriction of competition by object – Characterisation – Restriction of competition by effect – Conditions for exemption under Article 101(3) TFEU – Fines

In 1993, Cephalon, a United States biopharmaceutical company, obtained exclusive rights to the active pharmaceutical ingredient modafinil, sold for the treatment of certain sleep disorders in several countries in the European Economic Area (EEA).

The various national compound patents held by Cephalon for modafinil in the EEA expired at the latest in 2003. However, Cephalon still owned particle size secondary patents and other modafinil-related patents with an expiry date in 2015 in the EEA.

In 2002, Cephalon initiated patent infringement proceedings in the United States against Teva Pharmaceutical Industries Ltd ('Teva') and three other generic companies, with a view to preventing them from marketing their generic modafinil products in the United States. Since Teva launched its generic product in the United Kingdom in June 2005, Cephalon also initiated patent court proceedings in the United Kingdom. In turn, Teva filed a counterclaim for revocation.

At the end of 2005, Cephalon and Teva concluded a settlement agreement to end immediately their modafinil litigation in the United States and in the United Kingdom ('the settlement agreement'). Under that agreement, Teva committed not to enter the market independently and not to compete with Cephalon in the modafinil market ('the non-compete clause') and also not to challenge its modafinil patent rights ('the non-challenge clause') (together, 'the restrictive clauses').

The settlement agreement also provided for a package of commercial transactions relating to, inter alia, the granting of a non-exclusive licence from Teva to Cephalon in respect of its intellectual property rights for modafinil, the supply of modafinil by Teva to Cephalon and the distribution by Teva of Cephalon's products in the United Kingdom. The payments and royalties involved in the various transactions involved significant transfers of value to Teva. Moreover, the settlement agreement granted a non-exclusive licence to Teva to launch its generic modafinil product, including in the EEA, from 2012 at the latest.

Having found that the settlement agreement infringed the prohibition on agreements, decisions and concerted practices under Article 101 TFEU and Article 53 of the EEA Agreement, the Commission imposed fines on Cephalon and Teva amounting to EUR 30 480 000 and EUR 30 000 000, respectively. [16]

Cephalon and Teva brought an action for annulment against that decision, which is dismissed by the Third Chamber (Extended Composition) of the General Court. In that context, the Court clarifies the recent case-law on patent disputes settlement agreements under EU competition law.

Findings of the Court

In support of their action, the applicants criticised the Commission, inter alia, for committing an error of law and of fact in characterising the settlement agreement as a 'restriction of competition by object' for the purposes of Article 101(1) TFEU.

16 Commission Decision C(2020) 8153 final of 26 November 2020 relating to a proceeding under Article 101 TFEU and Article 53 of the EEA Agreement (Case AT.39686-CEPHALON) ('the contested decision').

In that respect, the Court recalls, first of all, that it follows from the judgment of the Court in Generics (UK) [17] that a patent dispute settlement agreement containing clauses restrictive of competition as well as commercial transactions constitutes a restriction by object where the transfers of value stemming from the commercial transactions provided for between the holder of the patent at issue and the party allegedly infringing the patent cannot have any explanation other than their commercial interest not to engage in competition on the merits. It is therefore, without any error in law that the Commission, in the contested decision, examined whether the commercial transactions contained in the settlement agreement would have been concluded without the restrictive clauses in order to ascertain whether they constituted an incentive for Teva to refrain from competing with Cephalon on the merits.

Furthermore, the linking of a business deal concluded between an originator company and a generic company with a settlement agreement containing, as in the present case, non-compete and non-challenge clauses, gives rise to the concern that that complex contractual arrangement, through a transfer of value provided for in the business deal, seeks to induce the generic company to accept those restrictive clauses. In that context, the question whether such a transaction would also have been concluded under normal market conditions forms part of the assessment which the Commission must carry out under Article 101 TFEU. To that end, it must assess whether the net gain from the transfers of value from the originator manufacturer to the generic manufacturer was sufficiently large actually to act as an incentive for the generic manufacturer not to compete on the merits with the originator manufacturer.

In the light of the foregoing, the Court, next, rejects the applicants' complaints challenging the Commission's conclusion that the sole purpose of the various commercial transactions provided for in the settlement agreement was, in fact, to serve as a transfer of value from Cephalon to Teva in consideration for Teva's commitment not to enter independently the markets for generic medicines and not to compete with Cephalon on modafinil.

In that regard, the Court finds that the Commission established, in the contested decision, that each of the business transactions provided for in the settlement agreement had no other purpose than to increase the level of the overall transfer of value to Teva in order to induce it to agree to the restrictive clauses. In addition, the Commission was right to find that the package of commercial transactions was sufficient to induce Teva to accept the non-compete and non-challenge commitments. Indeed, it is apparent from the course of the negotiations, as analysed by the Commission in the contested decision on the basis of the evidence, that both Cephalon and Teva sought to find a combination of transactions representing a certain overall value that was sufficiently beneficial for Teva to accept the restrictive clauses.

The Court rejects, last, Cephalon's and Teva's complaints referring to the judgment of the Court in Generics (UK), according to which the pro-competitive effects that the settlement agreement entail precluded its characterisation as a restriction of competition by object.

In that respect, the Court rejects, first, the argument that the settlement agreement accelerated Teva's independent market entry compared to the situation in which it would not win in the patent court proceedings in the United Kingdom. On that issue, the Court observes that, in order to determine whether pro-competitive effects precluded a finding of a restriction by object, the Commission did not have to examine scenarios where one or other party is successful in a patent dispute.

Second, the Court notes that, although Teva had concrete possibilities of entering the modafinil market in 2005 as an independent entrant, the settlement agreement and Teva's generic rights relating thereto did not provide for Teva's entering that market until 2012. Accordingly, that agreement delayed Teva's market entry by seven years, thus guaranteeing Cephalon that it would not face any competition from Teva during that period. Moreover, Teva's planned entry into the modafinil

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17 Judgment of 30 January 2020, Generics (UK) and Others (C-307/18, EU:C:2020:52).

market was not independent, in that it relied on a licence and subject to significant royalties. As a result, strong price competition between Teva and Cephalon was unlikely.

Since the other pleas raised by Cephalon and Teva have also proved to be unfounded, the Court dismisses the action in its entirety.

2. ABUSE OF A DOMINANT POSITION (ARTICLE 102 TFEU)

Judgment of the General Court (Fourth Chamber, Extended Composition) of 25 October 2023, Bulgarian Energy Holding and Others v Commission, T-136/19

Link to the judgment as published in extract form

Competition – Abuse of a dominant position – Internal market in natural gas – Decision finding an infringement of Article 102 TFEU – Regulated market – Definition of the relevant market – Romanian Transit Pipeline 1 – Holder of an exclusive right to use the Romanian Pipeline 1 – Refusal to grant access – Public supply obligation – State action defence – Transmission system operator – Storage system operator – Anticompetitive strategy – Exclusionary effects – Single and continuous infringement – Rights of the defence

At the time of the facts, the applicants, namely the company Bulgarian Energy Holding EAD, which was wholly owned by the Bulgarian State, and its subsidiaries Bulgargaz and Bulgartransgaz (together, 'the BEH Group'), were active in the energy sector in Bulgaria. Bulgargaz was the public gas supplier in Bulgaria whereas Bulgartransgaz was the gas transmission system operator ('the TSO') and the operator of the only natural gas storage facility in Bulgaria ('the Chiren storage facility').

During the infringement period (namely 30 July 2010 to 1 January 2015), the supply of gas in Bulgaria depended almost entirely on imports of Russian gas, of which Bulgargaz was the sole or main importer. Bulgargaz was thus also the main supplier of gas to downstream wholesale customers on the market and to end customers, namely undertakings directly connected to the gas transmission network.

The Russian gas was transported to Bulgaria via Ukraine, then Romania, up to the Bulgarian network connection point, mainly through a transit pipeline ('the Romanian Pipeline 1') which was managed by Transgaz, the Romanian TSO. During the infringement period, that pipeline ensured the supply of the majority of Bulgarian territory, via the national transmission network which, in turn, was connected to the Chiren storage facility. [18] Under an agreement concluded between Transgaz and Bulgargaz in 2005 ('the 2005 Agreement') which remained in force throughout the infringement period, Bulgargaz was granted exclusive use of the Romanian Pipeline 1, in return for a fixed annual fee.

On 18 November 2010, Overgas Inc., an operator in the gas supply market in Bulgaria, lodged with the European Commission an informal complaint against the BEH Group, alleging that it had infringed Article 102 TFEU.

[18] The Romanian Transit Pipelines 2 and 3 transported the Russian gas from the Ukrainian-Romanian border to the Romanian-Bulgarian border at the Negru Vodă 2 and 3 entry points, and merged on Bulgarian territory, forming the Bulgarian transit pipeline. That pipeline was used for limited supplies in the south-west of Bulgaria and mainly transported gas to the former Yugoslav Republic of Macedonia, Greece and Türkiye.

By Decision of 17 December 2018, [19] the European Commission concluded that the BEH Group had committed a single and continuous infringement of Article 102 TFEU between 30 July 2010 and 1 January 2015. More specifically, the Commission found that the BEH Group held, during that period, a dominant position on five separate markets, namely the market for capacity-related services on the gas transmission network, the market for capacity-related services on the Romanian Pipeline 1, the market for capacity-related services for the Chiren storage facility, the downstream wholesale market for the sale of gas, and the market for the retail supply of gas to large end customers connected to the Bulgarian gas transmission network. The Commission alleged that the BEH Group had abused its dominant position by preventing, restricting or delaying third-party access to the transmission network, to the Chiren storage facility and to the Romanian Pipeline 1, thus foreclosing the Bulgarian gas supply markets in order to protect Bulgargaz's dominant position on those markets. Consequently, the Commission imposed a fine on the BEH Group for the infringement thus established.

The General Court, ruling on the action for annulment brought by the BEH Group which sought, principally, annulment of the contested decision in its entirety, upholds that action in so far as the Commission failed to establish to the requisite legal standard that there was a refusal of access to the three infrastructures held by the BEH Group that was capable of falling within the scope of Article 102 TFEU. In doing so, the Court provides clarification as to the application of Article 102 TFEU to an undertaking in a dominant position which refuses access to an 'essential facility', in the light of the case-law in Bronner, [20] where that undertaking is not the owner of that facility. Furthermore, the Court rules on the scope of the requirement of access to the file which is inherent in respect for the rights of the defence in the 'data room' procedure, namely in the event of limitations on the right of access to certain elements of the file because of their confidential nature.

Findings of the Court

In the context of its assessment, the Court examines, as a first step, the substance of the case, namely the complaints alleging errors of law and of assessment in the definition of one of the five markets in question, in particular the market for capacity services on the Romanian Pipeline 1, Bulgargaz's dominant position on that market, the dominant position of the parent company BEH as a financial holding company on the relevant markets, and that group's abusive conduct. The Court then goes on to analyse the procedural defects relating to an infringement the BEH Group's rights of defence in terms of access to the file.

As regards the substance of the case, in the first place, the Court finds that, in the context of the definition of the market for capacity services on the Romanian Pipeline 1, the Commission was fully entitled not to draw a distinction between the primary market (namely the market for capacity traded directly by the TSO) and the secondary market (namely the market for capacity traded other than on the primary market), since that distinction is irrelevant for the assessment of whether the applicants held a dominant position in respect of the capacity services on the Romanian Pipeline 1. Furthermore, the Commission did not make errors of law or of assessment when it found that Bulgargaz held a dominant position on that market.

In that regard, it follows from the exclusive right over the Romanian Pipeline 1 that was granted under the 2005 Agreement that Bulgargaz was, throughout the infringement period, the only possible supplier of capacity services on that pipeline on the secondary market. Furthermore, first, under Article 17.1 of the 2005 Agreement, Transgaz could not offer third parties unused capacity without first obtaining Bulgargaz's consent. Second, under the EU legislation that was applicable at the time, Transgaz could offer such unused capacity to third parties only as short-term and interruptible

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19 Commission Decision of 17 December 2018 relating to proceedings under Article 102 of the Treaty on the Functioning of the European Union (Case AT.39849 – BEH Gas) (notified under number C(2018) 8806 final).

20 Judgment of the Court of Justice of 26 November 1998, Bronner (C-7/97, EU:C:1998:569).

capacity. Hence, Bulgargaz also controlled third-party access to the primary market for capacity services on the Romanian Pipeline 1. It follows that the Commission was fully entitled to identify Bulgargaz as a supplier on the Romanian Pipeline 1, as it was the only undertaking capable of providing third parties with access to that pipeline. The Court also stated that, although Transgaz had not yet fulfilled its obligations under EU law by taking the necessary measures to enable and facilitate the trade of capacity on the secondary market, in practice, Bulgargaz had, from 1 January 2013, granted Overgas access to the Romanian Pipeline 1. It follows that Transgaz's failure to fulfil its obligations did not prevent Bulgargaz from being able to offer capacity on that market. Thus, in view of the fact that, during the infringement period, Bulgargaz controlled third-party access to the Romanian Pipeline 1 and that Transgaz could not be identified as a genuine alternative source of supply for third parties wishing to have access to that pipeline, Bulgargaz held a dominant positon on the market for capacity services on the Romanian Pipeline 1.

In the second place, the Court states that the Commission failed to demonstrate that the BEH Group had abused its dominant position in respect of the supply of gas in Bulgaria. In that regard, the Court finds that the elements which the Commission set out regarding access to the Romanian Pipeline 1 in order to establish that all of the alleged restrictions on access existed and, to the extent that they were established, that they were abusive in nature, were insufficient.

First of all, the Court notes that the Commission rightly assessed Bulgargaz's conduct on the market for capacity services on the Romanian Pipeline 1 in the light of the Bronner case-law. In that regard, the Court states that a refusal by an undertaking in a dominant position to provide a service to which third parties must have access so as to be able to carry out an activity on a neighbouring market, in particular downstream, constitutes an infringement of Article 102 TFEU if three cumulative conditions are satisfied, namely if the refusal is capable of eliminating any competition by the applicant for that service on that market, if it cannot objectively be justified and if the service in question is essential for the exercise of the applicant's activity, in the sense that there is no actual or potential alternative to that service. In the present case, the Romanian Pipeline 1 was an 'essential facility' given that it was the only viable route for the transportation of Russian gas to Bulgaria during the infringement period. In that regard, the Commission was legitimately able to find that, for the purposes of the application of those case-law principles, it was of no consequence that Bulgargaz was not the owner of the infrastructure, but merely the holder of an exclusive right of use, since that right took the form of a situation of control over that infrastructure, enabling Bulgargaz to make third-party access to the pipeline conditional upon its agreement.

Next, the Court finds that the Commission's evidence as to the reservation of all of the capacity of the Romanian Pipeline 1 under the 2005 Agreement had no probative value since that reservation was not sufficient evidence to establish the alleged abuse on the market for capacity services on that pipeline. The contractual exclusivity granted to Bulgargaz under the 2005 Agreement, even though Bulgargaz used only part of the capacity on the Romanian Pipeline 1, could not constitute an abusive exploitation of Bulgargaz's dominant position if the Commission did not prove that Bulgargaz's conduct, in practice, had given it the ability to foreclose competitors from the Bulgarian gas supply markets, in particular within the meaning of the judgment in Bronner and the subsequent case-law [21] regarding a refusal of access to an 'essential facility'.

In the present case, it follows from the information set out by the Commission that the exclusivity granted to Bulgargaz did not prevent it, from 2013, from accepting a request made by the company Overgas, by granting it access to the unused capacity on the Romanian Pipeline 1. The Court also states that the Commission also failed to establish to the requisite legal standard that Bulgargaz abusively refused requests for access from other third parties.

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[21] Judgments of 15 September 1998, European Night Services and Others v Commission (T-374/94, T-375/94, T-384/94 and T-388/94, EU:T:1998:198, paragraphs 208 and 212), and of 10 November 2021, Google and Alphabet v Commission (Google Shopping) (T-612/17, under appeal, EU:T:2021:763, paragraph 215).

Lastly, the Court does not accept that any probative value can be given to the Commission's evidence as regards Bulgargaz's conduct in the context of the intergovernmental discussions between the Republic of Bulgaria and Romania relating to the renegotiation of the 2005 Agreement. According to the Court, those discussions cannot constitute evidence of a refusal to grant access to the Romanian Pipeline 1. The issues which that negotiation covered, in particular the need to grant Bulgargaz a guaranteed minimum capacity, were not reduced solely to Bulgargaz's interests, but required the involvement of the Bulgarian authorities in view of Bulgaria's dependence on the Romanian Pipeline 1 for the security of gas supply to the Bulgarian market. Furthermore, Romania had a clear interest in the renegotiation of the 2005 Agreement in view of the infringement proceedings which the Commission had initiated against it in 2009. In addition, the Court concluded that the Commission had not established to the requisite legal standard that the length of the negotiations was attributable to the applicants.

In the third place, the Court finds that the Commission also failed to establish to the requisite legal standard that the BEH Group had refused access to the transmission network and to the Chiren storage facility before June 2012. By contrast, as regards the latter facility, the Court states that the information in the file demonstrates that Bulgartransgaz's conduct was capable of restricting competition on the Bulgarian gas supply markets between June 2012 and September 2014. However, in so far as the contested decision reaches the conclusion that the applicants had committed a single and continuous infringement of Article 102 TFEU by refusing third parties access to the three infrastructures and emphasised the interdependence, complementarity and mutual reinforcement of all of the alleged conduct, the Court found that it cannot be inferred from the operative part of the contested decision that that operative part is based on a number of grounds concerning separate forms of abusive conduct each of which would, in itself, be sufficient to justify the operative part.

In those circumstances, the single ground relating to Bulgartransgaz's conduct in respect of the Chiren storage facility after June 2012 cannot, without substituting the Court's assessment of the facts for that of the Commission, constitute the essential, or even sufficient, statement of reasons capable of justifying, by itself, the operative part of that decision.

In conclusion, the Commission did not establish to the requisite legal standard the infringement in the form of an abuse of dominant position imputed to the applicants by the contested decision.

As regards the course of the procedure, the Court finds that the Commission committed procedural errors capable of causing an infringement of the BEH Group's rights of defence in so far as, first, the Commission did not include in the file, or included but in an inappropriate manner, the documents relating to certain meetings that it had had with Overgas and, second, granted insufficient access to those documents.

In particular, as regards the meetings which took place in 2015 and 2016, after the statement of objections was adopted, the Court states that those meetings were aimed at gathering information on the subject matter of the investigation which led to the adoption of the contested decision, and that it was not for the Commission to exclude information from the file by applying its power of discretion as to the potentially incriminatory or exculpatory nature of that document. Consequently, in accordance with Article 19 of Regulation No 1/2003, [22] read in conjunction with Article 3 of Regulation No 773/2004, [23] the Commission was required to record in an appropriate manner the statements made during those meetings and to include in the file the documents relating to them, and to inform the applicants of that fact, since the absence of any written record prevents the Court from ascertaining whether the Commission complied with the provisions of Regulation No 1/2003 and

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22 Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles [101 and 102 TFEU] (OJ 2003 L 1, p. 1).

23 Commission Regulation (EC) No 773/2004 of 7 April 2004 relating to the conduct of proceedings by the Commission pursuant to Articles [101 and 102 TFEU] (OJ 2004 L 123, p. 18).

whether the rights of the undertakings and natural persons involved in an investigation were fully respected.

As regards the meetings which took place from 2010 to 2013, before the statement of objections was adopted, the Commission included in the file only brief notes of those meetings whereas the detailed minutes remained confidential. In that regard, the Court states that those brief notes are manifestly insufficient to provide an account of the content of the discussions that actually took place between the Commission and Overgas and, in particular, to provide an account of the nature of the information provided by Overgas on the topics covered. Nothing in the wording of Article 19(1) of Regulation No 1/2003, or the objective which it pursues, supports the inference that the legislature intended to draw a distinction between, on the one hand, 'brief notes', made for the purposes of access to the file, and 'detailed minutes' intended to remain confidential, on the other. Such an interpretation would be tantamount to depriving the right of access to the file and the principle of equality of arms of all practical effect.

As regards the access to the documents made available in the data room, the Court stated that the applicants' external representatives had been authorised by the Commission to communicate only the non-confidential version of their data room report to their clients, and that that version did not contain any information that was additional to the brief notes to which the applicants had already had access during the administrative procedure. Redactions made to a data room report to the extent of making it practically equivalent to brief notes risk, according to the Court, compromising the very aim of the data room procedure, which is to protect the confidential information whilst giving access to evidence which a party needs in order to substantiate its position. That is all the more so since the data room procedure, as it took place in the present case, was capable of affecting the rights of defence of the applicants, which were able to exercise those rights only indirectly, through their external representatives.

As the applicants also demonstrated that, had the Commission not committed the errors by refusing the applicants a sufficient degree of access to the file, they would have had access to information that could have enabled them to better ensure their defence during the administrative procedure, the Court finds that the applicants' rights of defence were infringed.

In view of all of the foregoing considerations, the Court annuls the contested decision in its entirety.

IV. APPROXIMATION OF LAWS

1. MOTOR INSURANCE

Judgment of the Court of Justice (Fifth Chamber) of 12 October 2023, KBC Verzekeringen, C-286/22

Link to the full text of the judgment

Reference for a preliminary ruling – Insurance against civil liability in respect of the use of motor vehicles – Directive 2009/103/EC – Point 1 of Article 1 – Concept of a 'vehicle' – National legislation providing for the automatic compensation of certain road users who are the victims of a road accident – Person not driving a 'motor vehicle' within the meaning of that legislation – Concept equivalent to that of 'vehicle' within the meaning of Directive 2009/103 – Bicycle equipped with an electric motor providing pedal assistance, equipped with a boost function which can be activated only after the use of muscular power

On 14 October 2017, BV ('the victim'), who was riding an electric bicycle on a public road, was struck by a car insured by KBC Verzekeringen NV ('KBC'). The victim subsequently died. Since that accident was considered to be a 'commuting accident', P&V Verzekeringen CVBA ('P&V'), the occupational accident

insurer of the victim's employer, paid compensation and was subrogated to the rights of the victim and those of his successors in title.

P&V brought an action against KBC seeking the reimbursement of its expenses on the basis of the national legislation. In the present case, that legislation lays down, inter alia, an obligation for the insurers of the civil liability of drivers of motor vehicles involved in a road traffic accident to compensate in all cases the damages suffered by the victims of that accident where they are considered to be 'vulnerable road users'. The classification as a 'vulnerable road user' depends upon whether or not the victim of the accident was the driver of a 'motor vehicle' at the time of that accident. KBC lodged a counterclaim requesting that P&V be ordered to reimburse a sum which allegedly should not have been paid. In its defence, P&V argued that the victim could not be regarded as having been the driver of a motor vehicle.

Ruling on an appeal brought by KBC, the Hof van Cassatie (Court of Cassation, Belgium) made a reference for a preliminary ruling to the Court of Justice concerning the interpretation of the concept of 'vehicle', within the meaning of Article 1(1) of Directive 2009/103. [24]

By its judgment, the Court holds that that concept does not encompass a bicycle whose electric motor provides pedal assistance only and which is equipped with a function allowing the bicycle to accelerate to a speed of 20 km/h without pedalling, which may be activated only after the use of muscular power.

Findings of the Court

The Court notes, first of all, that it follows from the wording of point 1 of Article 1 of Directive 2009/103 that the concept of a 'vehicle', within the meaning of that provision, encompasses only vehicles intended for travel on land which may be propelled by mechanical power, with the exception of vehicles running on rails. However, that wording is not sufficient, by itself, to determine whether such mechanical power must be exclusively responsible for the propulsion of the vehicle concerned.

Next, the Court notes, first, that according to recital 2 of Directive 2009/103, the compulsory 'insurance against civil liability in respect of the use of motor vehicles' provided for in that directive refers to 'motor insurance', an expression which traditionally refers to insurance against civil liability in respect of the use of devices such as motorcycles, cars and trucks which, unless they are out of order, are propelled exclusively by means of mechanical power.

Secondly, Article 13 of Directive 2009/103 [25] specifies that each Member State is to take all appropriate measures to ensure that any statutory provision or any contractual clause contained in an insurance policy is deemed to be void in respect of claims by third parties who have been victims of an accident where that statutory provision or contractual clause excludes from insurance the use or driving of vehicles by persons who do not hold a licence permitting them to drive the vehicle concerned. It follows from Directive 2006/126, [26] that, in principle, only the driving of vehicles capable of running under their own power, other than rail-borne vehicles, is subject to a national driving licence.

Lastly, as regards the objectives pursued by Directive 2009/103, the Court emphasises that it is intended to guarantee that the victims of accidents caused by motor vehicles will receive comparable treatment irrespective of where in the European Union the accidents occurred, as well as ensuring the protection of those victims.

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24 Directive 2009/103/EC of the European Parliament and of the Council of 16 September 2009 relating to insurance against civil liability in respect of the use of motor vehicles, and the enforcement of the obligation to insure against such liability (OJ 2009 L 263, p. 11).

25 Directive 2009/103, Article 13(1)(b).

26 Directive 2006/126/EC of the European Parliament and of the Council of 20 December 2006 on driving licences (OJ 2006 L 403, p. 18), Article 4(1).

Devices which are not propelled exclusively by mechanical power and which therefore cannot travel on land without the use of muscular power, such as an electric bicycle which may accelerate to 20 km/h without pedalling, do not appear to be capable of causing bodily or material damage to third parties comparable, as regards gravity or scale, to the damage that may be caused by motorcycles, cars, trucks or other vehicles, travelling on land, propelled exclusively by mechanical power. The latter can reach speeds significantly higher than those that can be achieved by such devices and, at present, predominate on the road. The objective of protecting victims of road accidents caused by motor vehicles, pursued by Directive 2009/103, therefore does not require that such devices be covered by the concept of a 'vehicle', within the meaning of point 1 of Article 1 of that directive.

2. PLANT PROTECTION PRODUCTS

Judgment of the General Court (Seventh Chamber, Extended Composition) of 4 October 2023, Ascenza Agro and Industrias Afrasa v Commission, T-77/20

Link to the full text of the judgment

Plant protection products – Regulation (EC) No 1107/2009 – Implementing Regulation (EU) 2020/17 – Non-renewal of approval of the active substance chlorpyrifos-methyl – Action for annulment – Standing to bring proceedings – Admissibility – Obligation to examine all the conditions and criteria set out in Regulation No 1107/2009 – Absence of an EFSA conclusion – Transparency obligation – Right to be heard – Obligation to state reasons – Divergent risk assessments by the rapporteur Member State and EFSA – Obligation to take into account all the relevant factors of the case – Interim report on an ongoing study – Precautionary principle – Burden of proof and matter to be proved – Manifest error of assessment – Applicability of the read-across approach and of the weight-of-evidence approach – Possibility of relying on the ECHA and EFSA guidelines

Chlorpyrifos-methyl ('CHP-methyl') is an active substance used in plant protection products to control pests and to treat stored cereal grain and empty warehouses. CHP-methyl belongs to a group of chemicals called organophosphates, to which another active substance named chlorpyrifos also belongs.

Directive 91/414 concerning the placing of plant protection products on the market [27] established the legal regime for authorising the placing of plant protection products on the market in the European Union. CHP-methyl and chlorpyrifos were included in Annex I to that directive by Directive 2005/72. [28] The Commission's approval of CHP-methyl was extended on three occasions before expiring on 31 January 2020.

27 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1).

28 Commission Directive 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances (OJ 2005 L 279, p. 63). Directive 91/414 was replaced by Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ 2009 L 309, p. 1), under which the active substances listed in Annex I to Directive 91/414 were deemed to be approved. Those substances are now listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ 2011 L 153, p. 1).

Ascenza Agro, SA [29] and Dow AgroSciences Ltd, two undertakings producing CHP-methyl ('the applicants for renewal'), each submitted an application for renewal [30]of the approval of CHP-methyl. In its draft assessment report relating to that renewal, the Kingdom of Spain, as rapporteur Member State, did not conclude that CHP-methyl had any harmful effects on human health and therefore proposed that the approval of that active substance be renewed.

The European Food Safety Authority (EFSA) organised an initial consultation of experts to assess the risks to human health of CHP-methyl. It reported on those assessments in a statement of 31 July 2019, in which it stated that the approach taken by the experts was largely based on the structural similarities between CHP-methyl and chlorpyrifos.

The experts had, in addition, noted that there was no public literature available on the genotoxic potential of CHP-methyl whereas several publications were available for chlorpyrifos, for which concerns had been raised. They had agreed that those uncertainties had to be considered in the hazard assessment of CHP-methyl and that it therefore could not be ruled out that there was a potential risk of DNA damage. Consequently no reference value could be set for either genotoxicity or developmental neurotoxicity, which made it impossible to assess the risk for consumers, operators, workers, bystanders and residents.

Following a second consultation of experts, EFSA adopted, on 8 November 2019, an updated version of its statement of 31 July 2019, in which it concluded that the criteria applicable to human health as laid down in Article 4 of Regulation No 1107/2009 for the renewal of the approval of CHP-methyl were not met. On that basis, the Commission adopted, on 10 January 2020, Implementing Regulation 2020/17 concerning the non-renewal of the approval of the active substance CHP-methyl, in accordance with Regulation No 1107/2009 [31] ('the contested regulation').

In the contested regulation the Commission based the refusal to renew the approval of CHP-methyl on three grounds. First, the fact that 'a genotoxic potential of [CHP]-methyl cannot be ruled out', second, that 'concerns were identified concerning [its] developmental neurotoxicity' and, third, that 'it may be appropriate to classify [CHP]-methyl as toxic for reproduction, category 1B'.

By their action, the applicants, Ascenza Agro and Industrias Afrasa, SA, seek the annulment of the contested regulation.

The Court, ruling in extended composition, dismisses that action and, on this occasion, rules on a number of novel questions concerning Regulation No 1107/2009 and Implementing Regulation No 844/2012. Thus, as regards procedure, it clarifies the concept of a 'conclusion' within the meaning of Article 13 of Implementing Regulation No 844/2012 and specifies the impact that the reasons for a vote cast by a Member State in the context of the opinion issued by the Standing Committee on Plants, Animals, Food and Feed ('the standing committee'), before the Commission took its decision on the renewal of the active substance in question, has on the lawfulness of the contested regulation. Furthermore, as regards the substance, the Court provides clarification on the application of the transparency obligation and the precautionary principle in the context of plant protection products. It

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29 Then called Sapec Agro SA.

30 The approval of an active substance is renewed, on application, where it is established that the approval criteria provided for in Article 4 of Regulation No 1107/2009 and in Annex II thereto, which concern in particular the expected impact of those active substances on human health, are satisfied. The implementation of the renewal procedure for active substances is governed by Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ 2012 L 252, p. 26).

31 Commission Implementing Regulation (EU) 2020/17 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ 2020 L 7, p. 11). The Commission also adopted, on 10 January 2020, Commission Implementing Regulation (EU) 2020/18 concerning the non-renewal of the approval of the active substance chlorpyrifos, in accordance with Regulation No 1107/2009, and amending the Annex to Implementing Regulation No 540/2011 (OJ 2020 L 7, p. 14).

also rules on the scope of the 'read-across' approach and the 'weight-of-evidence' approach in the context of the application of Regulation No 1107/2009.

Findings of the Court

Existence of a 'conclusion'

In respect of the applicants' complaint alleging that EFSA did not submit a conclusion, the Court finds that there is no definition of a 'conclusion' in Implementing Regulation No 844/2012 [32] or in Regulation No 1107/2009. [33] Nevertheless, it is apparent from those texts, first, from a procedural point of view, that the conclusion must be adopted by EFSA and communicated to the applicant for renewal, the Member States and the Commission.

Second, as regards the content of the conclusion, EFSA is required, inter alia, to specify 'whether the active substance can be expected to meet the approval criteria provided for in Article 4' of Regulation No 1107/2009. Thus, the decisive factor for establishing the existence of a conclusion is the expression of an opinion by EFSA as to the potential of an active substance to meet the requirements and fulfil the criteria laid down by that regulation.

In the present case, since EFSA took the view, in its two statements of 31 July and 8 November 2019, that CHP-methyl did not meet those requirements with regard to human health, it did indeed adopt a conclusion within the meaning of Article 13 of Implementing Regulation No 844/2012. Such a finding cannot be called into question solely by the name used to describe the documents in question, entitled 'statements', since establishing the existence of a conclusion is dependent, first and foremost, on the content of those documents.

Transparency obligation

The Court recalls that it is incumbent on an affected party who invokes infringement of a transparency obligation in support of an action for annulment brought against an act of the European Union of general application to rely on an express provision conferring on it a procedural right and falling within the legal framework governing the adoption of that act.

The Court holds, first, that the contested regulation constitutes a measure of general application, without the fact that Ascenza Agro is individually concerned by that act being liable to call into question such a classification. Indeed, a distinction must be drawn between, on the one hand, the question of the general or individual application of an act, which depends on the act as such, and, on the other hand, the question of whether an ordinary applicant is individually concerned, which depends on the applicant's situation in relation to that act. Accordingly, although, in the light of the criteria laid down in the fourth paragraph of Article 263 TFEU, certain measures are, as regards their nature and their scope, of a legislative character, inasmuch as they apply to all the economic operators concerned, they may, without losing their regulatory character, in certain circumstances, concern individually certain economic operators who, if they are also directly affected by those measures, have standing to bring an action for annulment against them.

Second, compliance with the transparency obligation is, in the field of plant protection, guaranteed by specific provisions laid down by the legal framework governing the adoption of the contested regulation, namely Regulation No 1107/2009 laying down general provisions relating, in particular, to the procedure for renewal of the approval of an active substance, and Implementing Regulation No 844/2012 laying down specific provisions relating to the implementation of the procedure for renewal of the approval of an active substance.

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32 See the first subparagraph of Article 13(1) of Implementing Regulation No 844/2012.

33 See the second subparagraph of Article 12(2) of Regulation No 1107/2009.

However, the Court notes that the applicants have not relied, in the present case, on any express provision conferring a procedural right on Ascenza Agro and falling within the legal framework governing the adoption of the contested regulation.

Procedure for adopting the opinion of the standing committee

The Court notes that, in the present case, it is common ground that a favourable opinion from the standing committee on the draft contested regulation was obtained with the vote of the United Kingdom of Great Britain and Northern Ireland. Notwithstanding the foregoing, the Court notes that the applicants are in fact challenging the grounds of the contested regulation and not its adoption procedure.

It is apparent from the grounds of the contested regulation that its adoption was not based on the factors taken into account by the United Kingdom in its voting choice, with the result that the complaint put forward by the applicants is ineffective.

Precautionary principle

The Court recalls that where there is uncertainty as to the existence or extent of risks to human health, the precautionary principle allows protective measures to be taken without it being necessary to wait until the reality and seriousness of those risks become fully apparent. A correct application of the precautionary principle presupposes, inter alia, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because the results of studies conducted are insufficient, inconclusive on imprecise, but the likelihood of real harm to human health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures.

In the present case, the experts and EFSA carried out an assessment of the health risk of the proposed use of CHP-methyl, which revealed uncertainties. Such an approach is therefore consistent with the precautionary principle, which requires the authorities responsible for the risk assessment, such as EFSA, to communicate to the Commission not only the firm conclusions they have reached but also the remaining uncertainties, so that it can adopt restrictive measures if necessary.

Risk assessment methods used by EFSA and the Commission

The Court finds, in the first place, that EFSA was fully entitled to use the read-across approach and the weight-of-evidence approach for the purpose of assessing an active substance.

Indeed, as regards, first of all, what the two approaches entail, the read-across approach [34] makes it possible to predict the properties of certain substances from existing data relating to reference substances which are structurally similar to the first substances. As regards the weight-of-evidence approach, it makes it possible to predict the properties of certain substances on the basis of data from several independent sources of information. [35]

As regards, next, the purpose of those approaches, the REACH Regulation provides [36] that, with regard to human toxicity, information on intrinsic properties of substances is to be generated as far as possible by means other than vertebrate animal tests. The use of studies and tests can thus be

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34 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), Annex XI, Section 1.5.

35 See Section 1.1.1.3. of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1).

36 REACH Regulation, Article 13(1).

avoided by the use of various methods, [37] including the read-across approach and the weight-of-evidence approach. Accordingly, the read-across approach avoids the need to test every substance for every end point and may be used where there are no data on the substances subject to risk assessment. As for the weight-of-evidence approach, where it makes it possible to gather sufficient evidence to confirm the existence or absence of a particular dangerous property, that approach leads to the omission of further testing on animal. The Court concludes that the two approaches are intended, in particular, to limit the use of testing on vertebrate animals and that they therefore both make it possible to avoid testing every substance for every endpoint. REACH Regulation, Article 13(1).

As regards, moreover, the lawfulness of the use of the two approaches by EFSA, the Court notes that the provisions of Regulation No 1107/2009 [38] and Implementing Regulation No 844/2012 leave EFSA a wide margin of discretion in the choice of assessment methods which it applies, subject to its assessment being scientific in nature. Moreover, the Court points out that the Commission is also recognised as enjoying broad discretion, in view of the complex scientific assessments that have to be made in this area. Thus, where the Commission is moved to rely on the risk assessment carried out by EFSA, the Court's review of that assessment must also be limited to manifest errors of assessment.

In that regard, the Court takes the view that, in so far as the use of the two approaches is provided for in both Regulation No 1272/2008 and the REACH Regulation, the EU legislature considered that those approaches were sufficiently reliable, from a scientific point of view, to be used for the purposes of assessing chemical substances in fields other than that of plant protection products.

Lastly, the two approaches, which make it possible to avoid testing every substance for every effect, both contribute to the reduction of animal testing and thus to the achievement of one of the objectives pursued by Regulation No 1107/2009 and, consequently, by its implementing regulation, Implementing Regulation No 844/2012.

In the second place, as regards the specific rules for applying the two approaches, the Court observes, as regards the read-across approach, that it is not disputed that CHP-methyl and chlorpyrifos belong to the same group of chemical substances and that, overall, those substances have a similar chemical structure.

As regards the weight-of-evidence approach, the Court notes that EFSA merely found that the tests and studies produced by the applicants for renewal did not make it possible to establish the existence of risks to human health, without reference being made to scientific peer-reviewed open literature, within the meaning of Article 7(1)(m) of Implementing Regulation No 844/2012. It therefore did not consider that the data produced by the applicants for renewal were sufficient to enable it to draw adequate and definitive conclusions and, in particular, to enable it to conclude that CHP-methyl posed no genotoxic risk.

On the contrary, EFSA noted in its statements of 31 July and 8 November 2019 that the experts had stated that there was no public literature available concerning the genotoxic potential of CHP-methyl whereas several publications were available for chlorpyrifos. It added that, since concerns had been raised for chlorpyrifos with regard to chromosome aberrations and DNA damage, the experts had concluded that there were data gaps for CHP-methyl. It then stated that the experts had agreed that the resulting uncertainties had to be taken into account in the risk assessment of CHP-methyl and that it therefore could not be excluded that there was a potential risk of DNA damage. Furthermore, the experts and EFSA did not consider that the scientific studies relating to the genotoxicity of CHP-methyl should have a greater impact on their conclusions than all of the other elements relating to the genotoxicity of CHP-methyl. Rather than basing the assessment of the risks associated with CHP-

37 Listed in Section 1 of Annex XI to the REACH Regulation.

38 See Article 4.

methyl solely on the tests and studies which the regulations required the applicant for renewal to submit, they also took account of all the relevant scientific literature available.

V. COMMON COMMERCIAL POLICY

1. SAFEGUARD MEASURES

Judgment of the General Court (First Chamber) of 4 October 2023, Euranimi v Commission, T-598/21

Link to the full text of the judgment

Safeguard measures – Steel products market – Import of certain steel products – Implementing Regulation (EU) 2021/1029 – Action for annulment – Interest in bringing proceedings – Locus standi – Admissibility – Prolongation of a safeguard measure – Necessity – Threat of serious injury – Adjustment measures – European Union interest – Manifest error of assessment

In the context of the European Union's commercial defence policy, the European Commission made imports of certain steel products originating in various third countries ('the product concerned') subject to prior monitoring. In the light of the statistical data collected on that basis, it initiated a safeguard investigation, at the end of which it concluded that there was a threat of serious injury to the EU steel industry in most of the product categories concerned. Consequently, it imposed, successively, a provisional safeguard measure against imports of the steel products in question, [39] and then a definitive safeguard measure, [40] in the form of tariff quotas specific to category. [41] The safeguard mechanism thus established consists of two stages, the first consisting of the imposition of tariff quotas which are fixed at levels designed to enable normal trade flows to be preserved by product category, the second consisting of the application of an additional duty to imports, at the rate of 25%, where the quantitative thresholds fixed for those tariff quotas are exceeded ('the above-quota tariff'). [42] On 24 June 2021, by Regulation 2021/1029, [43] the Commission prolonged that measure for a period of three years until 30 June 2024 ('the contested regulation').

The applicant, the European Association of Non-Integrated Metal Importers & Distributors (Euranimi), an association of EU companies representing the interests of importers, distributors, traders and processors dealing with non-integrated steel, stainless steel and metal products, brought an action seeking annulment of the contested regulation.

The General Court, while declaring that action admissible, dismisses it on its merits. In its judgment, it provides, inter alia, clarification of the conditions required in order to establish both an interest in bringing proceedings and the standing to bring proceedings of an association representing the

39 Commission Implementing Regulation (EU) 2018/1013 of 17 July 2018 imposing provisional safeguard measures with regard to imports of certain steel products (OJ 2018 L 181, p. 39).

40 Commission Implementing Regulation (EU) No 2019/159 of 31 January 2019 imposing definitive safeguard measures against imports of certain steel products (OJ 2019 L 31, p. 27).

41 Implementing Regulation (EU) 2019/159 established a country-specific tariff quota for countries with significant interest as suppliers and a 'residual' tariff quota for the other countries exporting to the European Union.

42 Regulation (EU) 2019/159, recitals 164 to180.

43 Commission Implementing Regulation (EU) 2021/1029 of 24 June 2021 amending Commission Implementing Regulation (EU) 2019/159 to prolong the safeguard measure on imports of certain steel products (OJ 2021 L 225 I, p. 1).

interests of importers, distributors, traders and processors of the product concerned in a case for the purposes of an action seeking the annulment of an act imposing a safeguard measure.

Findings of the Court

As a first step, the Court examines and concludes that the action is admissible, rejecting for that purpose the Commission's argument that the applicant has no interest in bringing proceedings or standing to bring proceedings.

As regards the applicant's interest in bringing proceedings, the Court considers that annulment of the contested regulation would, in itself, be capable of having legal consequences and would be capable of securing a benefit for the applicant.

In the first place, such an annulment would be comparable to a complete liberalisation of tariff quotas, which would enable the applicant to carry on its activity under legal rules free of constraints linked to quantitative thresholds.

In the second place, the applicant's interest is vested and present, in that the possibility of applying the above-quota tariff exists on the date on which the action was lodged. That interest is also certain, since the quota system was effective on the date of application of the contested regulation.

In the third place, the existence of the applicant's interest in bringing proceedings cannot be conditional on the imposition of the above-quota tariff. First, the applicant does not merely challenge the imposition of that tariff, but extends to challenging the quota system which, by its very existence, alters the legal position of its members. Second, to make the existence of an interest in bringing proceedings conditional on the imposition of the above-quota tariff would have the effect of obliging the applicant's members to import volumes above the quantitative thresholds in order to be able to challenge that system and to ignore the unfavourable situation represented by the very application of such a system.

Finally, the Commission argues to no avail that the Court, in an earlier judgment, [44] rejected the assumption that the tariff quotas produced effects. In that judgment, the Court did not rule on the admissibility of the action before it, but on the existence of a manifest error of assessment in the Commission's analysis, with the result that the considerations relied on by the Commission are irrelevant in the context of the examination of the applicant's interest in bringing proceedings in the present case.

As to the applicant's standing to bring proceedings, the Court notes that the applicant, as a representative association, has standing to bring proceedings against the contested regulation on the basis of the third limb of the fourth paragraph of Article 263 TFEU. In that regard, it recalls that, in accordance with that provision, a representative association may bring an action for annulment against an act which is not addressed to it, provided that the contested act is a regulatory act which is of direct concern to its members and does not entail implementing measures.

In the present case, the Court finds, first of all, that the contested regulation is in the nature of a regulation in the light of its general application and the detailed rules for its adoption, which is not a legislative act.

Next, it finds that that regulation directly affects the applicant's members in that, in the first place, it directly affects their legal situation: it determines the legal framework and the conditions under which those members may import into the European Union, in terms both of volume and pricing, since their products are now subject to a quota system and no longer to release for free circulation within the European Union, which requires neither the determination of quantities nor authorisation from the Commission. In the second place, the contested regulation leaves no discretion to the competent authorities of the Member State in the implementation of the safeguard measure, both in the context

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44 Judgment of 20 October 2021, Novolipetsk Steel v Commission, T-790/19, EU:T:2021:706.

of the first stage of the safeguard mechanism, the quota system becoming effective on the date of application of the contested regulation, and in the context of the second stage of that mechanism, since the competent authorities are required to apply an above-quota tariff once the tariff quotas have been exhausted.

Finally, the Court confirms that that regulation does not entail implementing measures with regard to the applicant's members. The production of the legal effects of the quota system does not depend on any implementing measure. It follows that, before the tariff quota is exhausted, there are not any implementing measures which the applicant's members, whose legal situation is affected by the establishment of the quota system, could challenge before the national courts.

As to the substance, the Court rejects, in the first place, the plea alleging infringement of Article 19 of the Basic Safeguards Regulation, [45] since the Commission did not make a manifest error of assessment in concluding that the conditions for prolonging the safeguard measures under that provision were satisfied. [46]

In the second place, the Court rejects the plea alleging manifest errors committed by the Commission in the assessment of the European Union interest in prolonging the safeguard measure, since the applicant has failed to demonstrate the existence of such errors.

In the light of those considerations, the Court dismisses the action in its entirety.

2. DEFENCE AGAINST TRADE BARRIERS

Judgment of the General Court (Third Chamber) of 18 October 2023, Zippo Manufacturing and Others v Commission, T-402/20

Link to the full text of the judgment

Commercial policy – Regulation (EU) 2020/502 – Measures adopted by the United States on imports of certain derivative aluminium and steel products – European Union decision to suspend equivalent trade concessions and other obligations – Additional customs duties on imports of products originating in the United States – Action for annulment – Standing to bring proceedings – Admissibility – Principle of good administration – Right to be heard

In April 2020, in response to the imposition by the United States of America of an increase in the custom duties on imports of certain derivative aluminium and steel products, the European Commission considered that it was necessary to adopt measures to implement Regulation No 654/2014 [47] concerning the exercise of the Union's rights for the application and enforcement of international trade rules. After having sought the views of the relevant stakeholders pursuant to

45 Regulation (EU) 2015/478 of the European Parliament and of the Council of 11 March 2015 on common rules for imports (OJ 2015 L 83, p. 16).

46 Under that provision, a safeguard measure may be extended if it is determined that such prolongation is necessary to prevent or remedy serious injury (Article 19(2)(a)) and if it is determined that there is evidence that Union producers are adjusting (Article 19(2)(b)).

47 Regulation (EU) No 654/2014 of the European Parliament and of the Council of 15 May 2014 concerning the exercise of the Union's rights for the application and enforcement of international trade rules and amending Council Regulation (EC) No 3286/94 laying down Community procedures in the field of the common commercial policy in order to ensure the exercise of the Community's rights under international trade rules, in particular those established under the auspices of the World Trade Organization (OJ 2014 L 189, p. 50).

Article 9 of that regulation, it adopted Implementing Regulation 2020/502 [48] providing for the application of additional customs duties on imports of metal mechanical windproof lighters ('the products concerned') originating in the United States.

The applicants, the company Zippo Manufacturing Co. ('ZMC'), established in the United States, and its subsidiaries, Zippo GmbH and Zippo SAS, are engaged in the manufacture, distribution and sale of the products concerned toward the European Union. Having not participated in the information gathering sought by the Commission, they brought an action for annulment of the contested regulation in so far as its provisions concerned them.

The Commission put forward a plea of inadmissibility against that action, on the ground that the applicants did not have standing to bring proceedings under the fourth paragraph of Article 263 TFEU, since the contested regulation was of neither individual nor direct concern to them.

By rejecting that plea of inadmissibility, the Court declares the action admissible. As regards the substance, it finds the argument alleging an infringement of the principle of good administration well-founded and therefore annuls the contested regulation in so far as it covers the products manufactured and distributed by the applicants. In that regard, the Court finds an infringement of the right to be heard under Article 41(2) of the Charter of Fundamental Rights of the European Union ('the Charter') in the information gathering exercise carried out by the Commission prior to the adoption of the contested regulation.

Findings of the Court

In the first place, the Court examines the admissibility of the action, recalling, from the outset, that, under the fourth paragraph of Article 263 TFEU, a natural or legal person may institute proceedings against a measure of general application, such as a regulation, only if the measure is of direct and individual concern to him or her.

As regards individual concern, the Court holds that it is apparent from the information in the file that there is a set of factual and legal elements constituting a particular situation which differentiates ZMC from all other economic operators and which shows that the contested regulation is of individual concern to it. ZMC has demonstrated to the requisite legal standard that it is, in particular, the sole producing exporter of the products concerned from the United States to the European Union and that the State of Pennsylvania, where ZMC is established, is one of the US states which was taken into account for the purposes of selecting the products subject to the rebalancing measures.

As for the condition relating to direct concern, it requires the fulfilment of two criteria, namely that the contested measure must directly affect the legal situation of the person concerned and leave no discretion to the addressees who are entrusted with the task of implementing it.

In that context, the Court notes, in the first place, that the Member States, entrusted with the task of implementing the contested regulation, have no discretion as regards the rate of additional customs duties at issue on imports into the European Union and the imposition of those duties on the products at issue. In the second place, it finds, first, that ZMC, as the sole exporting producer of the products concerned, is directly concerned by the negative impact intended by the Commission when it adopted the contested regulation. Second, the contested regulation, by affecting the right of access of those products to the EU market, also affects the right of access for ZMC's products and, accordingly, produces direct legal effects on ZMC.

In the light of, in particular, those considerations, the Court concludes that the contested regulation is of individual and direct concern to ZMC and that it therefore has standing to bring proceedings for the purposes of the fourth paragraph of Article 263 TFEU.

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48 Commission Implementing Regulation (EU) 2020/502 of 6 April 2020 on certain commercial policy measures concerning certain products originating in the United States of America (OJ 2020 L 109, p. 10) ('the contested regulation').

In the second place, as regards the substance, the Court examines the applicants' complaint alleging an infringement of the principle of good administration, in particular of their right to be heard.

In that regard, it recalls that, according to settled case-law, the right to be heard, as a principle and fundamental right of the EU legal order, guaranteed by Article 41(2)(a) of the Charter, applies to any procedure which is liable to culminate in a measure adversely affecting a person, that is, an act which may have a negative effect on the interests of the individual or Member State concerned. Furthermore, that right must apply, even in the absence of specific legislation.

In the present case, the Court notes, first, that no provision of Regulation No 654/2014 explicitly excludes or restricts the right to be heard of undertakings whose products are subject to rebalancing measures provided for by an implementing act adopted by the Commission under that regulation. Furthermore, Article 9(1) of that regulation, in so far as it provides for the obligation for the Commission to seek information and views regarding the European Union's economic interests in specific goods or services or in specific sectors, does not constitute an implementation of the right to be heard of the undertakings concerned. Admittedly, it cannot be ruled out that an undertaking which has taken part in such information gathering has usefully and effectively asserted its interests or submitted information relating to its personal situation. However, where an undertaking, whose interests might be adversely affected by those rebalancing measures, has not participated in such information gathering, it cannot be considered that its right to be heard was not violated on the sole ground that the Commission has fulfilled its obligation to organise that information gathering.

Moreover, a rebalancing measure adopted on the basis of Regulation No 654/2014 is likely to adversely affect the interests of the undertakings exporting the products concerned by that measure, even if that measure was not taken following an individual procedure against those undertakings. It follows that those undertakings may rely on the right to be heard, in particular in a case, such as the present one, where the conduct of the procedure for adopting the implementing act led the Commission to identify those undertakings.

That conclusion cannot be called into question by the Commission's argument that it would not have had the necessary time to hear the applicants during the procedure for adopting the contested regulation, which had to be adopted within the time limits laid down in the World Trade Organisation (WTO) Agreement on Safeguards.

It is for the Commission, first, to ensure compliance with the time limits resulting from the WTO Agreement on Safeguards and, secondly, to hear the applicants, which had the right to be heard during the procedure for adopting the contested regulation. Since the Commission has failed to prove that it was impossible for it to hear the applicants effectively during that procedure, the Court considers that it had the time necessary to allow the applicants to exercise their right to be heard.

As regards the consequences to be drawn from that procedural irregularity, it follows from well-established case-law that an infringement of the rights of the defence leads to the annulment of the decision adopted at the end of the procedure only if, had there been no irregularity, that procedure could have led to a different outcome. That requirement is met when the undertaking concerned demonstrates that it would have been better able to defend itself had there been no irregularity.

In the present case, the Court considers that, if the applicants had been able to exercise their right to be heard during the procedure, they would have been able to rely on the arguments put forward in the application and, thus, would have been better able to defend themselves. Furthermore, since ZMC is the sole producing exporter of the products at issue, it cannot be ruled out that the contested regulation could have differed in content.

In the light of those considerations, the Court finds that the infringement of the applicants' right to be heard was likely to have an impact on the outcome of the procedure and, therefore, annuls the contested regulation in so far as it covers the products concerned.

Nota bene:

The résumé of the following case is currently being finalised and will be published in a future issue of the Monthly Case-Law Digest:

- Judgment of 25 October 2023, BNP Paribas Public Sector v SRB, T-688/21, EU:T:2023:675