

Novis Insurance Company, Novis Versicherungsgesellschaft,  
Novis Compagnia di Assicurazioni, Novis Poist'ovňa a.s.

v

European Commission

Order of the General Court (Seventh Chamber) of 23 May 2025

(Action for annulment – European System of Financial Supervision – Investigation in respect of an infringement of EU law – Formal opinion of the Commission on actions necessary to comply with EU law – Article 17(4) of Regulation (EU) No 1094/2010 – Actionable measure – Lack of direct concern – Inadmissibility)

*1. Action for annulment – Actionable measures – Concept – Acts producing binding legal effects – Formal opinion of the Commission addressed to a national authority on actions necessary to comply with EU law – Included*

*(Art. 263 TFEU; European Parliament and Council Regulation No 1094/2010, Art. 17(4))*

*(see paragraphs 31-33, 35)*

*2. Action for annulment – Natural or legal persons – Acts of direct and individual concern to them – Direct concern – Criteria – Formal opinion of the Commission on actions necessary to comply with EU law addressed to a national authority – Retention of the discretion of that authority as to whether or not to withdraw the authorisation of the financial institution which has infringed EU law – Action by that institution against the formal opinion – Lack of direct concern – Inadmissibility*

*(Art. 263 TFEU, fourth para.; European Parliament and Council Regulation No 1094/2010, Art. 17(4))*

*(see paragraphs 46-52, 75)*

## Résumé

Hearing an action for annulment, which it dismisses as inadmissible, on the ground that the applicant is not directly concerned, the Court rules for the first time on whether formal opinions issued by the European Commission, addressed to a national authority on the basis of Article 17(4) of Regulation No 1094/2010 ( [1](#) ) and setting out the necessary action to comply with EU law, may be challenged before the EU Courts. On that occasion, the Court clarifies the legal nature of the acts adopted by the European Insurance and Occupational Pensions Authority (EIOPA) and by the Commission on the basis of Article 17 and, thus, whether those acts may be the subject of an action for annulment.

The applicant, Novis Insurance Company, Novis Versicherungsgesellschaft, Novis Compagnia di Assicurazioni, Novis Poist'ovňa a.s., is a life insurance company established in Slovakia and subject to the supervision of the Národná banka Slovenska (Slovak National Bank) ('NBS'). EIOPA had carried out an investigation that sought to determine whether the NBS had exercised its supervisory powers over the applicant in accordance with the Solvency II Directive. ( [2](#) ) At the end of that investigation, EIOPA adopted a recommendation, addressed to the NBS, on actions necessary to comply with the Solvency II Directive; ( [3](#) ) that recommendation was the subject of an action for annulment brought by the applicant before the General Court and registered as Case T-204/24.

On 13 September 2022, the Commission adopted a formal opinion, addressed to the NBS, on actions necessary to comply with the Solvency II Directive ('the contested act'). ( [4](#) ) By that formal opinion, the Commission considered that, as long as that national authority had not adopted supervisory action

putting an end to the infringements in a structural and sustainable manner, it would remain in breach of EU law. It finds a persistent infringement of EU law by the NBS and sets out the action to be taken by the NBS in order to bring that infringement to an end. According to the Commission, this means adopting, with regard to the applicant, within four months, a final decision entailing supervisory action such as to ensure compliance with EU law, such as a decision to withdraw the applicant's authorisation.

Following that formal opinion, the NBS withdrew the applicant's authorisation.

## ***Findings of the Court***

Hearing a plea of inadmissibility raised by the Commission, the Court examines, first of all, whether the contested act constitutes an act which may be the subject of an action for annulment under Article 263 TFEU.

The Court observes that actions for annulment are available in the case of measures or provisions which are intended to have binding legal effects. Although that is not, in principle, the case of opinions, the impossibility of bringing an action for annulment against an opinion does not apply if the contested act, by reason of its content, does not constitute a genuine opinion.

In this respect, in order to determine whether an act produces binding legal effects, it is necessary to examine the substance of that act and to assess its effects on the basis of objective criteria, such as the content of that act, taking into account, as appropriate, the context in which it was adopted and the powers of the EU institution, body, office or agency which adopted it. In addition, the subjective criterion relating to the intention of the author of the act may also be taken into consideration.

As regards the context in which the contested act was adopted and the powers of its author, the Court observes that Article 17 of Regulation No 1094/2010 establishes a 'three-step mechanism' where a national authority is alleged, in its supervisory practices, to have failed to apply or to have applied incorrectly or insufficiently EU law, in particular the Solvency II Directive.

Thus, in the first step, EIOPA investigates, where appropriate, the alleged infringement or non-application of EU law. (5) At the end of that investigation, EIOPA may address to the national authority concerned a 'recommendation setting out the action necessary to comply with Union law'. (6)

In the second step, if the national authority concerned has not complied with EU law within one month from receipt of EIOPA's recommendation, the Commission may issue a 'formal opinion requiring [that authority] to take the action necessary to comply with Union law'. (7)

In the third step, if the national authority concerned does not comply with the formal opinion issued by the Commission within the period of time specified by that opinion and if certain conditions are met, EIOPA may adopt an 'individual decision addressed to [the financial institution concerned] requiring it to take all necessary action to comply with its obligations under Union law, including the cessation of any practice'. (8)

It is thus apparent from the wording of Article 17 of Regulation No 1094/2010 that recommendations issued by EIOPA on the basis of Article 17(3) merely 'set out' the action to be taken, whereas formal opinions issued by the Commission on the basis of Article 17(4) and individual decisions adopted by EIOPA on the basis of Article 17(6) 'require' their respective addressees to take the necessary action.

In addition, the second subparagraph of Article 17(7) of Regulation No 1094/2010 provides that, when taking action in relation to issues which are subject to a formal opinion issued by the Commission or to an individual decision of EIOPA, the national authorities concerned 'shall comply with the formal opinion or the decision, as the case may be'. However, neither that provision nor any other provision of that regulation provides that those authorities are required to comply with recommendations issued by EIOPA.

In the light of all the foregoing considerations, the Court holds that recommendations issued by EIOPA on the basis of Article 17(3) of Regulation No 1094/2010 are mere recommendations and are not themselves intended to produce binding legal effects vis-à-vis the national authority concerned or the financial institution concerned. By contrast, formal opinions issued by the Commission on the basis of Article 17(4) of that regulation and individual decisions adopted by EIOPA on the basis of Article 17(6) of that regulation produce binding legal effects vis-à-vis those to whom they are addressed.

In those circumstances, and also taking into account the content of the contested act, its wording and the intention of its author, the Court concludes, in the present case, that the contested act produces binding legal effects vis-à-vis the NBS, in so far as it requires it to adopt, with regard to the applicant, within a period of four months, a final decision entailing supervisory action such as to ensure compliance with EU law. Accordingly, contrary to what the Commission maintains, that act may be the subject of an action for annulment under Article 263 TFEU.

Second, the Court examines whether the applicant has standing to bring proceedings and, in particular, whether it is directly affected by the contested act. The Court observes that the condition that a natural or legal person must be directly concerned by the act being challenged requires two cumulative criteria to be met, namely, first, that the contested act must directly affect the legal situation of that person and, second, that it must leave no discretion to its addressees who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from EU rules alone without the application of other intermediate rules.

In the present case, the contested act requires the NBS to adopt a final decision with regard to the applicant, within four months, entailing supervisory action such as to ensure compliance with EU law. It follows that the contested act leaves no discretion to the NBS as regards the very principle of the adoption of a decision and supervisory action within a specified period.

By contrast, the Court takes the view that the contested act undeniably leaves the NBS a discretion as regards the nature of the supervisory action to be adopted. That act neither requires nor prohibits the NBS from taking specific action. In particular, the Commission did not require the NBS to withdraw the applicant's authorisation. In that context, the NBS's discretion was limited only by the applicable legal provisions, which allow, in certain cases, and require, in other cases, the supervisory authority of the home Member State to withdraw the authorisation of an insurance or reinsurance undertaking.

The Court infers from this that the NBS retained a discretion in defining the action to be taken with regard to the applicant and that, therefore, only the action taken by the NBS could directly affect the applicant. Thus, there is no direct connection between the contested act and the effects of the implementing measures subsequently taken by the NBS with regard to the applicant. The Court concludes that, at the very least, the second cumulative criterion required, under the condition relating to whether the applicant is directly concerned, is not satisfied in the present case, with the result that that condition is not satisfied. Accordingly, it dismisses the action as inadmissible.

---

( [1](#) ) Regulation (EU) No 1094/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/79/EC ([OJ 2010 L 331, p. 48](#)).

( [2](#) ) Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) ([OJ 2009 L 335, p. 1](#); 'the Solvency II Directive').

( [3](#) ) Under Article 17(3) of Regulation No 1094/2010.

( [4](#) ) Under Article 17(4) of Regulation No 1094/2010.

( [5](#) ) Under the first subparagraph of Article 17(2) of Regulation No 1094/2010.

( [6](#) ) Under the first subparagraph of Article 17(3) of Regulation No 1094/2010.

( [7](#) ) Under the first subparagraph of Article 17(4) of Regulation No 1094/2010.

( [8](#) ) Under the first subparagraph of Article 17(6) of Regulation No 1094/2010.