Case C-64/20

Request for a preliminary ruling

Date lodged:

6 February 2020

Referring court:

An Ard-Chúirt (The High Court (Ireland))

Date of the decision to refer:

20 January 2020

Applicant:

UH

Respondents:

An tAire Talmhaíochta, Bia agus Mara, Éire agus an tArd-Aighne

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AN ARD-CHÚIRT

(THE HIGH COURT)

JUDICIAL REVIEW

[National court reference number] [OMISSIS] [IN PROCEEDINGS] BETWEEN

UH

APPLICANT

-and-

AN tAIRE TALMHAÍOCHTA, BIA AGUS MARA, ÉIRE AGUS AN tARD-AIGHNE (THE MINISTER FOR AGRICULTURE, FOOD AND THE MARINE, IRELAND AND THE ATTORNEY GENERAL)

RESPONDENTS

REQUEST FOR A PRELIMINARY RULING PURSUANT TO

ARTICLE 267 TFEU

Decision of the High Court of Ireland to request a preliminary ruling pursuant to Article 267 of the Treaty on the Functioning of the European Union, delivered on 20 January 2020.

This court requests the Court of Justice to grant an expedited hearing pursuant to Article 105 of the Rules of Procedure of the Court of Justice of the European Union as the matter will become moot soon by reason of Regulation (EU) 2019/6 (which will apply as from 28 January 2022), which will replace the provisions of Directive 2001/82 relevant to this case. **[OR. 2] [OR. 3]**

[Address of the Court of Justice and of the national court, names of the parties and their representatives] [OMISSIS]

[OMISSIS] **[OR. 4]**

Questions referred for a preliminary ruling:

(1) Does a national court have discretion to refuse relief in spite of its decision that national law has failed to give effect to a particular aspect of a directive of the European Union (EU) and, if the court does have that discretion, what are the appropriate factors that should be taken into account in relation to the discretion and/or is the national court entitled to take into account those same factors which it would take into account if it were dealing with a breach of national law?

(2) Would the principle of direct effect in EU law be undermined if the national court refused to grant relief in this case due to the entry into force of Article 7 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 (the application of which is deferred until 28 January 2022), in spite of the fact that the national court decided that national law has failed to give effect to the duty in Articles 61(1), 58(4) and 59(3) of Directive 2001/82/EC, that duty being that the packaging and labelling of veterinary products must be in the official languages of the Member State, that is to say, in Irish as well as English, in Ireland?

[OR. 5]

Facts of the case

1 The Applicant is a native Irish speaker from the Galway Gaeltacht. He speaks Irish at home and at work. He conducts all his official business in Irish in so far as the resources are available to that end. He has a pet dog and, accordingly, requires veterinary medicinal products. His complaint was that the information accompanying the veterinary products was solely in English and not in both

official languages of the State, that is to say, Irish and English. In his opinion, that constituted an infringement of Directive 2001/82/EC, which was permitted under the law of the Member State (statutory instruments SI 144/2007 and SI 786/2007).

2 Following correspondence between the parties, the Applicant brought an application before the High Court of Ireland on 14 November 2016 seeking leave for judicial review regarding the Minister's failure to transpose the Directive correctly in respect of its language requirements. That leave was granted to him and the case was heard in the High Court of Ireland on 24 and 25 July 2018.

3 The Applicant sought the following relief arising from the failure of the Minister and the State to transpose the Directive correctly:

1. *A declaration that the European Communities (Animal Remedies) Regulations 2007-2014, made by the First Respondent, do not transpose Title V of Directive 2001/82/EC (as amended) ('the Directive'), specifically Articles 58-61, correctly or at all.*

2. *A declaration that Irish law must ensure that the appropriate particulars on the package leaflets and packaging in question in Title V, Articles 58 to 61, of the Directive are in the official languages of the State, that is to say, in both Irish and English, on veterinary medicinal products placed on the market in the State.*

[OR. 6]

3. *A declaration that the First, Second and Third Respondents must amend the State's law to reflect Title V, Articles 58 to 61, of the Directive, specifically so that the national law provides that the appropriate particulars on the package leaflets and packaging in question in Articles 58 to 61 of the Directive must be in both official languages of the State, that is to say, in both Irish and English, for veterinary medicinal products placed on the market in the State with both languages in the same size font and with a clear priority given to the Irish version since it is the national language and the first official language.*

Directive 2001/82/EC

4 Article 61(1) of the Directive (as amended) provides as follows, in so far as it relates to this case (there is as yet no official Irish version):

> *The inclusion of a package leaflet in the packaging of veterinary medicinal products shall be obligatory unless all the information required by this Article can be conveyed on the immediate packaging and the outer packaging. Member States shall take all appropriate measures to ensure that the package leaflet relates solely to the veterinary medicinal product - with which it is included. The package leaflet shall be written in terms that*

> *are comprehensible to the general public and in the official language or languages of the Member State in which the medicinal product is marketed*.
>
> (Emphasis added)

The particulars to appear on the package leaflet are set out in Article 61(2)(a) to (i).

5 Article 58(4) of the Directive, '*Labelling and Package Insert*', provides as follows:

[OR. 7]

> *The particulars mentioned in paragraph 1(f) to (l) shall appear on the outer package and on the container of the medicinal products in the language or languages of the country in which they are placed on the market*.

The particulars in the abovementioned paragraph 1(f) to (l) relate to instructions for consumers, that is to say, the animal owner, such as the Applicant in this case.

6 Article 59(3) provides as follows:

> *The particulars mentioned in the third and sixth indents of paragraph [route of administration and the words 'For animal treatment only'] 1 shall appear on the outer package and on the container of the medicinal products in the language or languages of the country in which they are placed on the market.*

The purported transposition into national law

7 Although many statutory instruments were made as a result of the Directive, the transposition, as regards the language of the packaging, which gives rise to the complaint in this case is in Statutory Instruments 144/2007 and 786/2007. According to Statutory Instruments 144/2007 and 786/2007, the particulars required may be in Irish or in English, which is erroneous, in the Applicant's view.

The Applicant's arguments concerning the Directive and the statutory instruments

8 The Applicant claimed that the abovementioned statutory instruments have failed to transpose Directive 2001/82/EC correctly as the particulars required may be in Irish or in English instead of in both languages.

[OR. 8]

9 The Applicant also made submissions regarding *locus standi* in response to the State's denial that the Applicant had standing to bring proceedings. In that regard,

he claimed that the part of the Directive that had not been transposed had direct effect as the binding provisions in question were clear, precise and unconditional – *Van Gend en Loos* (Case 26/62) [EU:C:1963:1], *Van Duyn* v *Home Office* (Case 41/74) [EU:C:1974:133], *Tullio Ratti* (Case 148/78) [EU:C:1979:110] – and referred to the principle of equality between official languages of the European Union and their speakers under European law (Article 3 of the Treaty on European Union, and Articles 21 and 22 of the Charter of Fundamental Rights of the European Union).

The Respondents' arguments in the national court regarding the effect of granting the relief sought by the Applicant.

10 The Respondents submitted that the Applicant did not have *locus standi*. They also submitted that the court should examine the issue in a much broader context as it could have profound implications for the entire agricultural sector, for the economy as a whole and, indeed, for human and animal health. They submitted that the court should consider whether it would be reasonable to grant the relief sought, having regard to the critical importance of ensuring that an appropriate range and supply of veterinary medicines continue to be available within the jurisdiction.

11 The Respondents argued that the critically important agri-food and agri-business industries, which are vital sources of income, must be fostered and developed. The livelihoods of hundreds of thousands of people and of their families depend on those industries. Animal health is hugely important for the survival of those industries. Farmers, livestock owners and veterinarians must have access to the widest possible range of animal medicines produced and distributed in accordance with the relevant European standards. In that regard, Ireland, **[OR. 9]** as a country, relies on a continued supply of animal medicines by the major veterinary medical firms to the Irish market, which is a market of minor importance from their perspective. If those major suppliers were required to provide information leaflets and packaging in Irish as well as in English, it is most probable that many of them would withdraw from the Irish market entirely.

12 They submitted that packaging and labelling account for the highest proportion of the administrative costs in offering veterinary medicines for sale on national markets. This was shown in a major impact assessment carried out by the European Commission several years ago. That impact assessment found that packaging and labelling costs amounted to 34% of the administrative costs associated with placing a product on a pluri-national market. By comparison, for example, only 17% of the costs related to applications for marketing authorisations, and 13% to the renewal of market authorisations.

13 Small countries such as Ireland should not be placed at a disadvantage in comparison with monolingual countries and with other large markets as a result of the requirement of having to provide, in more than one language, information leaflets, packaging and labelling relating to veterinary medicinal products which

are used in one market only. Needless to say, any material that is made available in Irish cannot be used in any other country. However, the abovementioned impact assessment suggested that the cost and burden of providing multilingual packaging and information leaflets may lead to companies deciding not to offer their products for sale in certain national markets. Therefore there is a real danger that the obligation to provide such material in Irish would lead to a significant, and perhaps even very significant, reduction in the range of animal medicines that would be available in Ireland. This could have a devastating impact on the agricultural sector and on other sectors, for example, on the horse industry in Ireland, and on the economy as a whole.

[OR. 10]

The decision of the national court concerning the alleged failure to transpose Directive 2001/82/EC correctly

14 On 26 July 2019, the national court ruled that the Applicant had *locus standi* since the binding provisions in question were clear, precise and unconditional and that the Applicant could therefore invoke the Directive against the Respondents [OMISSIS]. The court also ruled that Ireland had failed to transpose the Directive correctly into national law as regards the language requirements. The High Court held on 26 July 2019 that the national law (SI 144/2007 and SI 786/2007) infringes the Directive by allowing the information in question on the packaging to be provided in English only, instead of in both of the official languages in Ireland, namely Irish and English.

15 The national court also noted, however, that the European Parliament and the Council have adopted Regulation (EU) 2019/6 of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, that is to say, after the national court had heard this action. Article 160 of that new regulation ('Entry into force and application') provides that that regulation will not apply until 28 January 2022. The national court noted that there are new language provisions in the new regulation and that, when it enters into force, the information on the packaging may be permitted to be provided in English only. Article 7 of the new regulation provides as follows:

Languages

1. The language or languages of the summary of the product characteristics and the information on the labelling and on the package leaflet shall, unless the Member State determines otherwise, be an official language or languages of the Member State where the veterinary medicinal product is made available on the market.

2. Veterinary medicinal products may be labelled in several languages.

[Emphasis added]

[OR. 11]

16 The court then raised the question whether it would be worthwhile granting the relief sought in the light of that forthcoming change, and, if it were deemed not to be worthwhile, whether the national court may decide not to grant the relief sought where Ireland is in breach of EU law. The national court requested that the parties present written submissions and oral argument to the court on the issue of whether or not a national court has discretion to grant relief in judicial-review proceedings if that court decides that there was a failure with respect to a directive, and, if it does have that discretion, on the issue of the appropriate factors to be taken into account in relation to that discretion and/or whether the national court is entitled to take into account those same factors which it would take into account if it were dealing with a breach of national law.

17 A hearing on that issue was held on 16 October 2019 and the national court sought further submissions as to whether the question should be referred to the Court of Justice of the European Union as a request for a preliminary ruling.

Arguments before the national court concerning discretion to refuse to grant relief

The Applicant's arguments concerning discretion to refuse to grant relief

18 The Applicant argued that it is a principle of law that EU law prevails over the national law of the Member States and that, in the event of a conflict, national law must yield to EU law (Case 6/64, *Costa* v *ENEL* [EU:C:1964:66]). The Applicant submitted that EU law currently provides that the information on the packaging in question for veterinary medicinal products must be in both Irish and English and that the Applicant is entitled to rely on that law from now until 27 January 2022 and to exercise the rights arising therefrom. The Applicant submitted **[OR. 12]** that nobody in Ireland (including the courts) has the power to deny him that right.

19 As regards the terms and spirit of the Treaties to which the Court of Justice referred in *Costa* (above), the Applicant argued that the court should have regard to the Treaty provisions on language rights and equality (Article 3 of the Treaty on European Union and Articles 21 and 22 of the Charter of Fundamental Rights of the European Union). As regards the supremacy of EU law, the Applicant referred to *Simmenthal* (Case 106/77, [EU:C:1978:49]) and the requirement to set aside any provision or practice under national law inasmuch as it conflicts with EU law (paragraphs 21 to 23).

20 The Applicant submitted that an effective judicial remedy must be available in the case where a right under EU law has been denied (Case C-249/88, *Commission* v *Belgium* [EU:C:1991:121]; the second subparagraph of Article 19(1) of the Treaty on European Union; Article 47 of the Charter of Fundamental Rights of the European Union).

21 The Applicant referred to the principle of direct effect (Case 26/62 *Van Gend en Loos* [EU:C:1963:1] and Case 6/64 *Costa* v *ENEL* [EU:C:1964:66]), arguing that the national courts are required to set aside any part of national law or any practice by a national court that would impair or delay the exercise of rights under EU law (*Simmenthal*, paragraphs 17, 18, 21 to 23 and 26; *R* (*Factortame Ltd)* v *Secretary of State for Transport* [1990] C-213/89 [EU:C:1990:257], paragraph 20).

22 The Applicant submitted that it would be incompatible with the principles of direct effect and supremacy of EU law to deny him effective protection and an effective remedy in the national court, even if it were only for a temporary period.

[OR. 13]

23 The Applicant submitted that he was entitled to the benefit of the current regime for as long as it lasts and that there was no evidence before the court that a binding court order would have no practical effect, even taking into consideration the delay that would be involved in redesigning the packaging.

24 The Applicant submitted that he was entitled to effective judicial protection (Article 47 of the Charter) pursuant to the Rule of Law, the principle of direct effect and the supremacy of EU law and that he was entitled to the appropriate relief *ex debito justitiae*.

25 In addition, the Applicant claimed that there was discretion whether to grant or refuse relief in other circumstances in judicial-review cases under Irish law, but that EU law does not permit such discretion owing to the direct effect of the EU law in question, the requirement for the national court to yield to the supremacy of EU law and to apply it by providing the Applicant with effective judicial protection (pursuant to Article 47 of the Charter) and pursuant to the Rule of Law.

Arguments made by the Respondents concerning discretion to refuse to grant relief

26 The Respondents acknowledged that, under national law, an applicant who successfully challenges the decision of a public authority through judicial review is usually entitled to relief, but they argue that this is not an absolute entitlement and that the court may always consider any material that might impede the granting of relief and, ultimately, may refuse to grant such relief.

[OR. 14]

27 There are long-established grounds in Irish law under which the courts may exercise that power, if they so decide, but may equally decide against doing so if they so wish. Those grounds include various factors, for example: (1) undue delay in bringing proceedings; or (2) failure to seek other more appropriate remedies, such as an appeal; or (3) a lack of candour on the part of the applicant; or (4) failure by the applicant to act in good faith; or (5) prejudice to third parties, and (6) where granting of relief would serve no useful purpose.

28 The Respondents explained the main reasons why it would be justifiable, in their view, to refuse relief in these proceedings were they governed by Irish law alone.

29 Firstly, they submitted that this case did not relate to a criminal conviction or any other decision that would be prejudicial to the Applicant and that would bring his reputation or his name into disrepute, or that would infringe his fundamental personal rights. As a result, in their view, none of the grounds for granting relief *ex debito justitiae*, traditionally, was present here.

30 Second, they submitted that it is widely accepted that relief may be refused when it would serve no useful purpose or would be of no practical benefit to the Applicant. In this case, there may be some benefit were relief granted to the Applicant but it would be very limited in terms of its value, owing to the entry into force of Regulation (EU) 2019/6 of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC and **[OR. 15]** the lifting of the requirement that the text on the product packaging must be in both official languages.

31 The Respondents submitted that it was clear that a transitional period would be necessary to enable all of the interested parties to prepare for the requirement that the labelling and packaging must be printed in both official languages. Relief should be refused if it would be of little practical benefit to the Applicant (even if it were of some small benefit), particularly if the granting of such relief would entail a real and substantial risk of serious prejudice to many other people or to the general public.

32 Third, there is a strong possibility in this case, if relief were granted, that it would have a serious impact on third parties. On the basis of affidavit evidence submitted to the court, if suppliers and distributors of veterinary medicinal products were to decide to withdraw from the Irish market due to the requirement to print the text of instruction leaflets and packaging in both official languages, it is clear that this would have grave consequences for animal health, as well as economic consequences, which would be detrimental to many individuals. The Respondents drew attention to the decision of the European Commission to proceed with the new regulation following broad consultation, during which the Commission identified a critical need for greater flexibility as regards the language requirements in relation to packaging and labelling of medicinal veterinary products. The Commission's review states as follows:

> *The highest burden concerns packaging and labelling. The requirements are that the text must be written in all the official languages of the country where the product is to be placed on the market.*

[OR. 16]

33 The Respondents submitted that the new developments in Regulation (EU) 2019/6 demonstrate clearly the legitimacy of the serious concerns expressed by the

respondents as regards any efforts made to provide information and packaging materials for animal medicines in both Irish and English.

34 Consequently, according to the Respondents, there were strong mitigating factors or circumstances to consider in this case. An order requiring suppliers to translate the important technical summary of product characteristics for a significant range of chemical substances and to print the packaging materials in question in Irish as well as in English could result in the suppliers withdrawing from the Irish market, and it is no exaggeration to say that this would lead to devastating economic and social consequences, as well as to devastating consequences for animal welfare. Owing to that clear risk, they submitted that, in this case, the public interest and the need to ensure that the widest possible range of veterinary medicinal products continues to be supplied to the public in Ireland far outweigh any argument that could be made in favour of granting relief to the Applicant as an individual.

35 The Respondents submitted that there is no Irish authority dealing with this particular point, but the question has arisen in a number of cases in the United Kingdom, including the decision of the Supreme Court of the United Kingdom in *Walton* v *The Scottish Ministers* [2012] UKSC 44, stating (per Lord Carnwath, paragraphs 133 and 140):

> *133. Accordingly, subject to any overriding principles emerging from the European authorities, it seems to me that, even if (contrary to what appears to be the effect of the statute) breach of the SEA Directive were a ground of challenge under the* **[OR. 17]** *1984 Act procedure, the court would retain a discretion to refuse relief on similar grounds to those available under domestic law.*
>
> *140. Accordingly, notwithstanding Mr Mure's concession, I would not have been disposed to accept without further argument that, in the statutory and factual context of the present case, the factors governing the exercise of the court's discretion are materially affected by the European source of the environmental assessment regime.*

36 The Respondents submitted that they did not wish to imply that a Member State should be anything but diligent in the application of and compliance with European law, or that the principle of effective judicial protection should be infringed in any way. However, there may be occasions, which are likely to occur only rarely, where there would be strong mitigating factors or circumstances in relation to the public interest and the protection of the rights of other members of the public, in which it would be justifiable for a court to refuse relief. They claimed that this case comes within the scope of that exception and that this court may refuse to grant the relief sought and that it ought to do so.

Decision of the High Court of Ireland to request a preliminary ruling pursuant to Article 267 of the Treaty on the Functioning of the European Union

37 After reviewing the submissions on a preliminary ruling and hearing counsel for the parties on 24 October 2019, the High Court has decided to refer the questions set out above to the Court of Justice of the European Union pursuant to Article **[OR. 18]** 267 of the Treaty on the Functioning of the European Union. It is the High Court's view that if a national court has discretion to refuse relief despite the fact that that court has decided that national law has failed to give effect to the duty under Articles 61(1), 58(4) and 59(3) of Directive 2001/82/EC to make packaging and labelling on veterinary products available in both official languages, it should exercise its discretion and refuse to grant the relief sought in this particular case in the light of the criteria relied on by the Respondents, but the court wishes to verify that this would not undermine the principle of direct effect or the principle of effective judicial protection.

ANNEXES

1. The Book of Pleadings

2. The order for reference, dated and perfected by the Registrar of the High Court on the 24th day of January 2020.

Dated: 20/01/2020

[ANNEX - the order for reference] [OMISSIS]

[OMISSIS]