JUDGMENT OF THE COURT (Second Chamber)

14 September 2006 *

In Case C-138/05,

REFERENCE for a preliminary ruling under Article 234 EC, by the College van Beroep voor het bedrijfsleven (Netherlands), made by decision of 22 March 2005, received at the Court on 25 March 2005, in the proceedings

Stichting Zuid-Hollandse Milieufederatie

v

Minister van Landbouw, Natuur en Voedselkwaliteit,

intervener:

LTO Nederland,

* Language of the case: Dutch.

THE COURT (Second Chamber),

composed of C.W.A. Timmermans, President of the Chamber, R. Schintgen, R. Silva de Lapuerta, J. Klučka (Rapporteur) and L. Bay Larsen, Judges,

Advocate General: E. Sharpston,
Registrar: R. Grass,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— Stichting Zuid-Hollandse Milieufederatie, by J. Rutteman, acting as Agent,

— the Netherlands Government, by H.G. Sevenster and M. de Mol, acting as Agents,

— the Danish Government, by A. Rahbøl Jacobsen, acting as Agent,

— the Greek Government, by V. Kontolaimos and S. Papaioannou, acting as Agents,

— the French Government, by G. de Bergues and R. Loosli-Surrans, acting as Agents,

— the Commission of the European Communities, by B. Doherty and M. van Beek, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 4 May 2006,

gives the following

Judgment

1 The reference for a preliminary ruling concerns the interpretation of the transitional provisions of 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) and those of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ 1998 L 123, p. 1).

2 The reference was made in the context of proceedings between the Stichting Zuid-Hollandse Milieufederatie ('the Stichting') and the Minister van Landbouw, Natuur en Voedselkwaliteit (Minister for Agriculture, Nature and Food Quality) ('the Minister') concerning a procedure under Netherlands law for the grant of authorisations to place pesticide products on the market.

Legal framework

Community rules

Directive 91/414

3 According to the ninth recital in the preamble to Directive 91/414:

'... the provisions governing authorisation must ensure a high standard of protection, which, in particular, must prevent the authorisation of plant protection products whose risks to health, groundwater and the environment [have not been researched properly]; ... human and animal health should take priority over the objective of improving plant production'.

4 In accordance with Article 2(1) of Directive 91/414, 'plant protection products' are 'active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user' and are intended principally to protect plants or plant products against harmful organisms. Article 2(4) of that directive defines active substances as 'substances or micro-organisms including viruses, having general or specific action' against harmful organisms or on plants, parts of plants or plant products.

5 Article 4(1) of that directive provides that Member States are to ensure that a plant protection product is not authorised unless its active substances are listed in Annex I and any conditions laid down in that annex and in Article 4(1)(b) to (f), are fulfilled.

6 Article 8 of Directive 91/414 concerns transitional measures and derogations. According to Article 8(2):

'By way of derogation from Article 4 and without prejudice to paragraph 3 or to Directive 79/117/EEC, a Member State may, during a period of 12 years following the notification of this Directive, authorise the placing on the market in its territory of plant protection products containing active substances not listed in Annex I that are already on the market two years after the date of notification of this Directive.

...'

7 Article 8(3) provides that '[w]here they review plant protection products containing an active substance in accordance with paragraph 2, and before such review has taken place, Member States shall apply the requirements laid down in article 4(1)(b)(i) to (v), and (c) to (f) in accordance with national provisions concerning the data to be provided'.

8 In accordance with Article 13(6) of Directive 91/414, 'for active substances already on the market two years after notification of this Directive, Member States may, with

due regard for the provisions of the Treaty, continue to apply previous national rules concerning data requirements as long as such substances are not included in Annex I'.

9 According to Article 23, Directive 91/414 was to be implemented 'within two years following notification thereof'.

Directive 98/8

10 Directive 98/8 concerns products, formerly known as non-agricultural pesticides, which are used for the control of organisms that are harmful to human or animal health and organisms that cause damage to natural or manufactured products.

11 Article 5(1) of that directive provides that Member States are to authorise a biocidal product only if 'the active substance(s) included therein are listed in Annex I or IA and any requirements laid down in those Annexes are fulfilled' and if a number of other conditions are satisfied.

12 Article 16(1) of Directive 98/8, on transitional measures, provides that 'a Member State may, for a period of 10 years ..., continue to apply its current system or practice of placing biocidal products on the market. It may, in particular, according to its national rules, authorise the placing on the market in its territory of a biocidal product containing active substances not listed in Annex I or IA ...'. However, those

active substances must be on the market within not more than 24 months from the date of entry into force of the directive, as active substances of a biocidal product for purposes other than scientific research and development or process-orientated research and development.

National rules

13 Article 2(1) of the Law on pesticides (Bestrijdingsmiddelenwet) of 1962 (Stb. 1962, No 288), as amended by the Law of 6 February 2003 (Stb. 2003, No 62) ('the BMW'), provides:

'It is prohibited to sell, place in stock or store, bring into the Netherlands or use any pesticide which is not shown to be authorised or, in the case of a low-risk biocidal product, registered under this Law.'

14 Article 3(1) of the BMW is primarily intended to transpose Article 4(1) of Directive 91/414. In particular, Article 3(1)(a)(1) to (10) sets out conditions which correspond essentially to those laid down in Article 4(1)(b)(i) to (v) of that directive, whilst Article 3(1)(b) to (d) fixes the conditions which correspond to those laid down in Article 4(1)(c) to (e) of that directive. Article 3(2)(a) of the BMW is intended to transpose Article 4(1)(a) of that same directive.

15 Article 16aa of the BMW, which entered into force on 8 February 2003, reads as follows:

'1. [The] Minister concerned may, where the interests of agriculture so urgently require, grant an exemption or derogation from Articles 2(1) and 10(1) and (2) in respect of a plant protection product containing an active substance:

a. which was already in circulation prior to 26 July 1993;

b. which has not been designated by a Community measure referred to in Article 3 (2)(a), and

c. in respect of which the examination referred to in Article 8(2) of Directive 91/414 was commenced or continued after 26 July 1993.

2. Conditions may be attached to an exemption or derogation. They may be granted subject to limitations and withdrawn at any time.'

The main proceedings and the questions referred for a preliminary ruling

16 On 21 April 2004, on the basis of Article 16aa of the BMW, the Minister adopted the Decision on exemptions for plant protection products 2004 (besluit Vrijstellingen

gewasbeschermingsmiddelen 2004, Stcrt. 2004, No 77) ('the decision of 21 April 2004') which granted to the users referred to therein and for the benefit of the crops described therein an exemption from the prohibitions laid down in Articles 2(1) and 10(1) of the BMW, in so far as the provisions on use and instructions for use laid down in chapter I of the annex thereto were complied with in respect of the delivery, placing in stock or storage, import into or use in the Netherlands of the plant protection products referred to in that same Chapter I. The decision of 21 April 2004 expired on 1 January 2005.

17 By decision of 28 April 2004, amending the decision of 21 April 2004 (besluit Wijziging Besluit vrijstellingen gewasbeschermingsmiddelen 2004, Stcrt. 2004, No 82) ('the decision of 28 April 2004'), the Minister added 13 sections to Annex I of the decision of 21 April 2004. Those sections concerned specific applications of certain plant protection products in respect of which exemptions from the abovementioned prohibitions were granted.

18 By letter of 9 June 2004, the Stichting and the Stichting Natuur en Milieu ('the foundations') lodged a complaint against the decision of 28 April 2004.

19 By ministerial decision of 18 October 2004, the foundations' complaints were held to be partly inadmissible and partly unfounded.

20 On 28 October 2004 the Stichting brought an action against that decision before the College van Beroep voor het bedrijfsleven (Administrative Court for Trade and

Industry) which, faced with a question of incompatibility of Article 16aa of the BMW with Community law, decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) May Article 8 of [Directive 91/414] be applied by the national court after the period referred to in Article 23 thereof has expired?

(2) Must Article 16 of [Directive 98/8] be interpreted as having the same meaning as Article 8(2) of [Directive 91/414]?

(3) Must Article 8(2) of [Directive 91/414] be interpreted as a standstill obligation in the sense that a Member State has the power to alter the existing system or practice only in so far as this results in an assessment in connection with the authorisation of plant protection products which is consistent with this directive?

(4) If the answer to Question 3 is in the negative:

Does Article 8(2) of [Directive 91/414] impose limits on amendments to national rules concerning the placing on the market of biocidal products, and if so what limits?

(5) If the answer to Question 4 is in the negative:

By what criteria is it necessary to assess whether there are measures liable seriously to compromise achievement of the result prescribed by [Directive 91/414]?

(6) If the answer to Question 2 is in the negative:

(a) Must Article 8(2) of [Directive 91/414] be interpreted as meaning that, where a Member State authorises the placing on the market in its territory of plant protection products containing active substances not listed in Annex I to that directive that were already on the market two years after the date of notification of that directive, regard must also be had to the provisions of Article 4 thereof?

(b) Must Article 8(2) of [Directive 91/414] also be interpreted as meaning that, where a Member State authorises the placing on the market in its territory of plant protection products containing active substances not listed in Annex I to that directive that were already on the market two years after the date of notification of that directive, regard must also be had to the provisions of Article 8(3) thereof?

(7) Must Article 8(3) of [Directive 91/414] be interpreted as meaning that an examination of a new application of a plant protection product already on the market, whereby it is considered whether there are unacceptable risks to the operator/worker, human health and the environment in connection with a temporary measure as referred to in Article 16aa of the Law on Pesticides, is to be regarded as a review within the meaning of Article 8(3) thereof?

(8) Must Article 8(3) of [Directive 91/414] be interpreted as meaning that it contains only rules relating to the provision of data before a review or must it be construed as meaning that the requirements set out therein are also relevant to the way in which a review must be organised and carried out?'

The request to have the oral procedure reopened

21 By letter of 18 May 2006, the Netherlands Government asked the Court to order the reopening of the oral procedure, pursuant to Article 61 of the Rules of Procedure, on the ground that the part of the Opinion of the Advocate General relating to the fifth question was based on an incorrect interpretation of the Netherlands and Community rules.

22 First, it claims that the findings of the Advocate General disregard the obligation imposed by Netherlands law on applicants for an authorisation to place a plant protection product on the market to provide the competent minister with a detailed file. Second, it argues that, contrary to the statements made by the Advocate General, the fourteenth recital in the preamble to Directive 91/414 concerns only the possibility of temporarily authorising plant protection products containing active substances not listed in Annex I to that directive and which were not yet on the market two years after the date of notification of that directive.

23 The Court may, of its own motion, on a proposal from the Advocate General or at the request of the parties, order the reopening of the oral procedure under Article 61 of its Rules of Procedure, if it considers that it lacks sufficient information or that the case must be dealt with on the basis of an argument which has not been debated between the parties (see, order of 4 February 2000 in Case C-17/98 *Emesa Sugar* [2000] ECR I-665, paragraph 18, and Case C-210/03 *Swedish Match* [2004] ECR I-11893, paragraph 25).

24 That is not the case here, however. First, the Netherlands Government essentially confines itself to commenting on the Opinion of the Advocate General, without referring to any facts or legal provisions on which she relied and which have not been debated between the parties. Second, the Court considers that it is in possession of all the information necessary for it to answer the all of the questions referred.

25 The application for the oral procedure to be reopened must therefore be dismissed.

The questions

Admissibility

26 In the observations which it has submitted to the Court, the French Government initially expresses doubts as to the admissibility of a number of the questions.

27 First of all, it observes that the national court refers in Question 1 to Article 8 of Directive 91/414 as a whole, without specifying which of the paragraphs of that article, which refer to significantly different situations, is at issue. The French Government further submits that Article 23 of that directive concerns only the application of the second indent of the first paragraph Article 10(1) of the directive, on mutual recognition of authorisations in connection with certain requirements of Article 4 of that directive. Consequently, it argues, this question is inadmissible on the ground that the answer is not necessary for the resolution of the main proceedings.

28 Lastly, the French Government maintains that Question 2 is inadmissible on the ground that the main proceedings relate to plant protection products and not to biocidal products.

29 In that regard, it must be borne in mind that, in accordance with settled case-law, in the context of the cooperation between the Court of Justice and the national courts under Article 234 EC it is solely for the national court, before which the dispute has been brought and which must assume responsibility for the subsequent judicial decision, to determine in the light of the particular circumstances of the case both the need for a preliminary ruling in order to enable it to deliver judgment and the relevance of the questions which it submits to the Court. Consequently, where the questions submitted for a preliminary ruling concern the interpretation of Community law, the Court is, in principle, bound to give a ruling (see, inter alia, Case C-415/93 *Bosman* [1995] ECR I-4921, paragraph 59; Case C-35/99 *Arduino* [2002] ECR I-1529, paragraph 24; and Case C-316/04 *Stichting Zuid-Hollandse Milieufederatie* [2005] ECR I-9759, paragraph 29).

30 However, the Court has also stated that, in exceptional circumstances, it may examine the conditions in which the case was referred to it by the national court, in order to assess whether it has jurisdiction (see, to that effect, Case 244/80 *Foglia* [1981] ECR 3045, paragraph 21). The Court may refuse to rule on a question referred for a preliminary ruling by a national court only where it is quite obvious that the interpretation of Community law that is sought bears no relation to the facts of the main action or its purpose, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted to it (see, inter alia, *Bosman*, paragraph 61; *Arduino*, paragraph 25; and *Stichting Zuid-Hollandse Milieufederatie*, paragraph 30).

31 In the present case, it is not 'quite obvious' that the questions submitted by the national court come within one of those examples.

32 First, although the College van Beroep voor het bedrijfsleven did not indicate in Question 1 the paragraphs of Article 8 of Directive 91/414 to which it meant to refer, it none the less provided the Court with all the material necessary for it to be able to give a useful reply. It is quite clear from the decision for reference that the College van Beroep voor het bedrijfsleven referred to paragraphs 2 and 3 of Article 8, since they relate to plant protection products containing active substances not listed in Annex I to the directive that are already on the market two years after the date of notification of the directive, and also to Article 23(1) of that directive, since it fixes the time-limit for transposition of the directive as being two years from that date of notification.

33 Second, although, in accordance with its wording, Article 16aa of the Bmw applies only to plant protection products (gewasbeschermingsmiddelen), it cannot be maintained that the interpretation of Article 16 of Directive 98/8 bears no relation to the facts of the main action or its purpose, or that the problem is hypothetical. Indeed, referring to paragraph 44 of the judgment in Case C-306/98 *Monsanto* [2001] ECR I-3279, in which the Court held that Directive 98/8 contains, in relation to the placing of products on the market, provisions which bear a large number of similarities to those of Directive 91/414, and asking essentially whether the provisions of Article 16(1) of Directive 98/8, under which a Member State may, during the transitional period, continue to apply its system or practice of placing biocidal products on the market, are also to be found in Article 8(2) of Directive 91/414, the national court demonstrated that its second question was well founded.

34 All of the questions referred are therefore admissible.

Substance

The second question

35 By its second question, which it is appropriate to examine first, the national court asks essentially whether, in spite of the different wording, the transitional regimes under Article 16(1) of Directive 98/8 on the one hand and under Article 8(2) of Directive 91/414 on the other have the same meaning.

36 The Court has already answered an identical question in the affirmative in paragraphs 59 to 63 of the judgment in *Stichting Zuid-Hollandse Milieufederatie.*

37 In the light of the foregoing, the answer to Question 2 must be that Article 16(1) of Directive 98/8 has the same meaning as Article 8(2) of Directive 91/414.

The third to fifth questions

38 By its third to fifth questions, which it is appropriate to examine together, the national court asks essentially whether Article 8(2) of Directive 91/414 is to be interpreted as constituting a 'standstill' obligation or whether that article contains other restrictions on the right of Member States to amend their existing authorisation systems during the transitional period. More specifically, it asks

whether that article precludes adoption of national legislation which does not require submission of a dossier by a person applying for authorisation to market a plant protection product during that period, and does not require the competent authority to check whether the plant protection product in question and its active substances harm human and animal health and the environment, the only legal condition for authorisation being the existence of an urgent requirement in the interests of agriculture.

39 It must be observed, first of all, that the existence of a 'standstill' obligation cannot be inferred from the actual wording of Article 8(2) of Directive 91/414, which contains no express formulation to that effect (see, by analogy, *Stichting Zuid-Hollandse Milieufederatie*, paragraph 37).

40 It follows that Article 8(2) of Directive 91/414 is not to be interpreted as constituting a 'standstill' obligation.

41 However, the Member States' right to amend their systems for the authorisation of plant protection products during the transitional period established by Article 8(2) of Directive 91/414 cannot be regarded as unlimited (see, by analogy, *Stichting Zuid-Hollandse Milieufederatie*, paragraph 41).

42 It must be borne in mind that although the Member States are not obliged to adopt measures to transpose a directive before the end of the period prescribed for transposition, it follows from the second paragraph of Article 10 EC in conjunction with the third paragraph of Article 249 EC and from the directive itself that during that period they must refrain from taking any measures liable seriously to

compromise the result prescribed by that directive (Case C-129/96 *Inter-Environnement Wallonie* [1997] ECR I-7411, paragraph 45). The same applies to a transitional period, such as that provided for in Article 8(2) of Directive 91/414 (see, by analogy, *Stichting Zuid-Hollandse Milieufederatie*, paragraph 42).

43 The Court notes that Directive 91/414 is aimed not only at improving plant production and removing barriers to intra-Community trade in plant products, but also at protecting human and animal health and the environment (see, to that effect, Case C-174/05 *Zuid-Hollandse Milieufederatie and Natuur en Milieu* [2006] ECR I-2443, paragraph 30).

44 In those circumstances, Member States may not, without seriously compromising the result prescribed by that directive, amend, during the transitional period provided for by Article 8(2) thereof, the applicable legislation in such a manner as to allow themselves to authorise a plant protection product which comes within the scope of application of that provision, without taking due account of the effects which that product may have on human and animal health and on the environment.

45 Furthermore, when the authorities of a Member State consider those effects, any decision on authorisation must be taken solely on the basis of a dossier comprising the information necessary to enable a genuine assessment of those effects to be made.

46 Article 13(6) of Directive 91/414, which provides that, in derogation from Article 13(1), during the transitional period Member States may, with due regard for the

provisions of the Treaty, continue to apply previous national rules concerning data requirements, must not be interpreted as allowing Member States to exempt persons applying for an authorisation for a plant protection product entirely from their obligation to prepare a dossier.

47 It is for the national court to assess whether the national rules at issue in the main proceedings comply with the conditions laid down in paragraphs 44 and 45 of this judgment.

48 The answer to the third to fifth questions must therefore be that Article 8(2) of Directive 91/414 does not constitute a 'standstill' obligation. However, the second paragraph of Article 10 EC and the third paragraph of Article 249 EC, and Directive 91/414, require that during the transitional period prescribed in Article 8(2) of that directive the Member States refrain from adopting any measures liable seriously to compromise the result prescribed by that directive. More specifically, Member States may not, during that transitional period, amend the legislation applicable in such a manner as to allow themselves to authorise a plant protection product which comes within the scope of that provision, without duly considering the effects which that product might have on human and animal health and on the environment. Likewise, a decision relating to an authorisation may be taken only on the basis of a dossier comprising all necessary information enabling a genuine assessment of those effects to be made.

The sixth question

49 By its sixth question, which is divided into two parts, the national court asks whether Article 8(2) of Directive 91/414 is to be interpreted as meaning that, where a

Member State authorises the placing on the market in its territory of plant protection products containing active substances not listed in Annex I to that directive that were already on the market two years after the date of notification of that directive, it must comply with Article 4 or 8(3) thereof.

50 The Court has already had the opportunity to answer an identical question in *Stichting Zuid-Hollandse Milieufederatie*. In paragraphs 46 to 57 of that judgment, the Court answered the question in the negative.

51 The answer to the sixth question must therefore be that Article 8(2) of Directive 91/414 is to be interpreted as meaning that, where a Member State authorises the placing on the market on its territory of plant protection products containing active substances not referred to in Annex I to that directive that were already on the market two years after the date of notification of the directive, it is not required to comply with the provisions of Article 4 or Article 8(3) of that directive.

The seventh question

52 By its seventh question, the College van Beroep voor het bedrijfsleven asks essentially whether 'review' within the meaning of Article 8(3) of Directive 91/414 also covers an assessment, such as that carried out when the decisions at issue in this case were adopted pursuant to Article 16aa of the BMW, seeking to determine whether a new application of a plant protection product already on the market entails unacceptable risks for users, workers, public health and the environment.

53 It must borne in mind that a review within the meaning of Directive 91/414 presupposes that the plant protection product at issue has already been the subject of an authorisation and that that authorisation is still valid at the time when the review is carried out (*Stichting Zuid-Hollandse Milieufederatie*, paragraph 67).

54 Furthermore, it is apparent upon reading Articles 4(5) and 8(3) of Directive 91/414 that the purpose of that review is not a re-evaluation of an active substance in isolation but rather a re-evaluation of the final plant protection product and that it is at the initiative of the national authorities and not at the initiative of the individuals concerned that the relevant product is reviewed (*Stichting Zuid-Hollandse Milieufederatie*, paragraph 68).

55 The answer to the seventh question must therefore be that it is for the national court to assess whether the evaluation carried out pursuant to Article 16aa of the BMW corresponds to all the characteristics of a 'review' within the meaning of Article 8(3) of Directive 91/414, in particular those referred to in paragraphs 53 and 54 of the present judgment.

The eighth question

56 By its eighth question, the national court asks essentially whether Article 8(3) of Directive 91/414 contains only provisions concerning the communication of data prior to a review or whether it must be interpreted as meaning that the conditions which it lays down also have an impact on the way in which a review must be organised and carried out.

57 The Court has already had the opportunity to consider an identical question. In paragraphs 71 to 74 of the judgment in *Stichting Zuid-Hollandse Milieufederatie*, it held that that article is to be interpreted as meaning that it contains only provisions relating to the supply of data prior to a review.

58 The answer to the eighth question must therefore be that Article 8(3) of Directive 91/414 is to be interpreted as meaning that it contains only provisions relating to the provision of data prior to a review.

The first question

59 By its first question, which is divided into two parts, the national court asks essentially whether Article 8(2) and (3) of Directive 91/414 has direct effect after expiry of the periods prescribed for transposing those directives into domestic law.

60 In the light of the answers given to the other questions, there is no need to answer Question 1.

Costs

61 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Second Chamber) hereby rules:

1. **Article 16(1) of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market has the same meaning as Article 8(2) of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.**

2. **Article 8(2) of Directive 91/414 does not constitute a 'standstill' obligation. However, the second paragraph of Article 10 EC and the third paragraph of Article 249 EC, and Directive 91/414, require that during the transitional period prescribed in Article 8(2) of that directive the Member States refrain from adopting any measures liable seriously to compromise the result prescribed by that directive. More specifically, Member States may not, during that transitional period, amend the legislation applicable in such a manner as to allow themselves to authorise a plant protection product which comes within the scope of that provision, without duly considering the effects which that product might have on human and animal health and on the environment. Likewise, a decision relating to an authorisation may be taken only on the basis of a dossier comprising all necessary information enabling a genuine assessment of those effects to be made.**

3. **Article 8(2) of Council Directive 91/414 is to be interpreted as meaning that, where a Member State authorises the placing on the market on its territory of plant protection products containing active substances not referred to in Annex I to that directive that were already on the market two years after the date of notification of the directive, it is not required to comply with the provisions of Article 4 or Article 8(3) of that directive.**

4. **It is for the national court to assess whether the evaluation carried out pursuant to Article 16aa of the Law on pesticides of 1962 (Bestrijdingsmiddelenwet), as amended by the Law of 6 February 2003, corresponds to all the characteristics of a 'review' within the meaning of Article 8(3) of Directive 91/414, in particular those referred to in paragraphs 53 and 54 of the present judgment.**

5. **Article 8(3) of Directive 91/414 is to be interpreted as meaning that it contains only provisions relating to the provision of data prior to a review.**

[Signatures]