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REFIT Platform

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STAKEHOLDER SUGGESTIONS

- HEALTH & FOOD SAFETY -

DISCLAIMER

This document contains suggestions from stakeholders (for example citizens, NGOs, companies) or Member State authorities communicated to the Commission and submitted to the REFIT Platform in a particular policy area.

It is provided by the secretariat to the REFIT Platform members to support their deliberations on the relevant submissions by stakeholders and Member States authorities.

The Commission services have complemented relevant quotes from each suggestion with a short factual explanation of the state of play of any recent, relevant ongoing or planned work by the EU institutions.

The document does not contain any official positions of the European Commission unless expressly cited.

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1. SUMMARY

This briefing includes nine suggestions in nine different areas:

Food Contact Materials:

- The Danish Business Forum (DBF) suggests the establishment of common requirements for the declaration of compliance concerning articles and material to come into contact with food by introducing pre-defined templates into EU legislation. The Commission is currently undertaking a study which results will determine future possible actions.

Food Labelling in the Hospitality Sector

- The Austrian Federal Economic Chamber (WKÖ) suggests amending the Food Information Regulation in the gastronomy sector in order to provide allergen information upon oral request only. The regulation entered into force in 2014 and is currently not being reviewed as it is yet too early to determine impacts.

Residues in live animals and animal products

- The Danish Business Forum (DBF) suggests modernising the Directive relating to the monitoring of substances in live animals and animal products. A revision of the Directive has been proposed in the context of the proposal for a Regulation on official food and feed control and is under discussion with the legislator.

The Trade Control and Expert System:

- A citizen suggests that instead of the current TRACES certificate, national veterinary authorities should be required to have a central database in order to verify whether the national health number corresponds to a fish farm recognised as disease-free at European level. The applicable legislation (Directive 2006/88/EC and Regulation (EC) No 1251/2008) was adopted in 2008.

Biocidal products

- The Austrian Federal Economic Chamber (WKÖ) suggests introducing two year tolerance period for non-compliant SMEs until 1 September 2017, in relation with their obligations provided in Article 95 of the Biocidal Products Regulation[1]. The Directive became applicable 1 September 2013 and contains a transitional period for certain provisions that will end in 2016.

Traditional Herbal medicines and health claims made on botanicals used in food

- A citizen suggests revising the Traditional Herbal Medicinal Product Directive in order to facilitate innovation and the entry into the EU market of such products and to implement the Regulation on health claims on botanicals. The Regulation on health claims is currently being evaluated under the REFIT Programme.

[1] According to Article 95, only products whose active substance supplier(s) or the product suppliers are listed on a list established at EU level by the European Chemicals Agency (ECHA) are allowed to be made available on the EU market as from 1 September 2015.

Registration of feed business operators

- The Finish Survey for better regulation suggests waiving the obligation to register as a feed business establishment for certain retailers making available plant-based products for feeding animals.

Rules for the transport of dogs between Member States

- A citizen suggests facilitating transport regulations from Ireland to UK for greyhounds.

Medicinal products for human uses

- The Finnish Survey for better regulation submitted a suggestion to re-issue the directive relating to medicinal products for human use as a regulation like the proposal for medicinal products for animal use.

2. FOOD CONTACT MATERIALS

2.1. Submission by the Danish Business Forum (DBF)

EU Regulation 1935/2004 allows Member States to adopt national provisions on so-called declarations of compliance concerning materials and articles intended to come into contact with food.

Some Member States, such as Denmark, require a declaration on all types of materials and articles intended to come into contact with food whereas other Member States, such as Germany, only require a declaration of compliance for certain types of material.

The Danish model ensures a very high level of food safety. However, it comes with a price for manufacturers and importers in Denmark that have to provide these declarations. Often suppliers from other Member States and third countries do not understand why Danish importers demand to see declarations of compliance when they are not met with the same demand from importers from other EU Member States.

Suggestion

Common requirements in relation to declarations of compliance should be established. In order to secure a high level of food safety, it is suggested that the Danish model of declaration of compliance is supported by pre-defined declarations of compliance in the EU legislation on all the various types of materials and articles intended to come into contact with food. The pre-defined declarations should be possible to use in all situations, even if the materials are covered by more specific measures.

2.2. Policy Context

The policy context is set by the EU legislation as follows :

- A declaration of compliance (DoC) is a written document issued by the producer, which confirms that a food contact material put on the market complies with the relevant requirements.

- Regulation (EU) No 1935/2004, the *'Framework Regulation'* on food contact materials, sets out the basic provisions concerning DoC's in Article 16. Under this Article, a DoC is only required under specific EU measures which are enacted pursuant to Article 5 of the Framework Regulation and relating to the materials listed in Annex I of that Regulation.

- The Framework Regulation specifies that for articles not subject to specific EU measures, Member States may require a DoC under national legislation. The Framework Regulation does not provide any further requirement in this context. Based on the information available to the Commission services, it seems that the national legislation of most Member States requires DoCs and therefore specify at national level which information is to be provided.

Current state of play

The Commission services launched a study with the aim to provide a comprehensive description of the current situation concerning those food contact materials for which there are currently no specific measures at EU level. This study will provide the Commission with a starting point for determining whether further action is necessary. The results are due in early 2016.

3. EU FOOD LABELLING REGULATION FOR FOOD OPERATORS IN THE HOSPITALITY SECTOR

3.1. Submission by the Austrian Federal Economic Chamber (WKÖ)

As anticipated, compliance with the requirements of the Regulation has proven to be a significant additional administrative burden in the workplace for food businesses. This stands in a strong disproportion to the interest of consumers and guests to food labelling in general.

According to a survey of the German Hotel and Restaurant Association (DEHOGA) from April 2015 almost 70% of restaurant owners state that they have not received a single request by a guest for allergen information since the entry into force of the Regulation in December 2014. This finding is also consistent with our experience and we believe that throughout the European Union one will encounter similar results.

For this reason we think it is justified if the information obligation under the Food Information Regulation in the field of gastronomy is loosened. The severe obligation to inform should be changed into an instruction to inform, starting from the principle of oral information upon request.

3.2. Policy Context

The suggestion refers to the obligation for food business operators in the catering and restaurant sector to provide allergen information, an obligation established by Regulation (EU) No 1169/2011 on the food information to consumers which entered into application in 13 December 2014.

The Regulation lists 14 substances/products causing allergies and intolerances and products thereof of which the presence needs to be indicated on the label of pre-packed food; such information needs also to be given for non pre-packed foods. According to the Regulation, Member States may adopt national rules concerning the means through which information on allergens is to be made available for non pre-packed foods. This should allow Member States to address local practical conditions and circumstances. However, since the information has to be provided on a mandatory basis, it may not be provided to the consumer simply upon request. Information upon request could only be considered sufficient if the consumer is provided with an indication in a conspicuous manner that he or she may obtain allergen information upon request.

Current state of play

Evidence presented in the Commission's impact assessment suggests that most food allergy incidents can be traced back to non-prepacked food, often served in restaurants or at catering counters[2]. Therefore, the obligation was introduced in response to consumer demands to make such information available also on these foods. Continuous efforts are made by the Commission services to clarify the interpretation of the Regulation and to contribute to a pragmatic and harmonised application. The effects of the implementation of the Regulation could be reviewed at a later stage, in accordance with the normal policy cycle on EU legislation.

4. RESIDUES IN LIVE ANIMALS AND ANIMAL PRODUCTS

4.1. Submission by the Danish Business Forum (DBF)

The Directive on residues, which regulates veterinary medicinal products in relation to foods stuffs of animal origin (Directive 1996/23/EC), sets out a very detailed level of sampling in order to avoid residues of veterinary medicines in foodstuffs. The directive specifies which substances have to be examined in relation to species and products, as well as the method, scope and frequency of sampling. However, the directive is outdated and consequently food production oversight includes analysis of substances that are no longer used in food production. Furthermore, some Member States charge businesses with the cost of oversight whereas others do not, which distorts cross-border competition.

Suggestion

The directive should be modernised in order to promote risk-based sampling for residues.

[2]Source: Impact Assessment report on general food labelling issues COM (2008) 40 final, page 19.

Furthermore, as a general rule Member States should collect fees that cover the full cost of the inspections to level the playing field.

4.2. Policy Context

The suggestion refers to Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products. The Directive is applicable since July 1997 and replaced pre-existing legislation in this area.

Monitoring of residues of veterinary medicines in food of animal origin is regulated at EU level. Residues are monitored in view of checking compliance with rules on the correct use of the veterinary medicines and the safety of food of animal origin.

Monitored substances cover authorised substances (e.g. antibiotics, anthelmintics) as well as prohibited and/or banned substances (e.g. hormones for growth promotion).

Current state of play

A suggestion to harmonise monitoring rules for all food sectors is proposed in the framework of the **Commission proposal for a Regulation on Official Food and Feed Controls (adopted in May 2013, COM(2013) 265 final)** currently under discussion by the co-legislator**.** The proposal aims at eliminating the inefficiencies in the system of veterinary residues controls, repealing the Directive and replacing its provisions with more simplified rules[3].

If adopted the draft Regulation foresees that the organisation of the future residue monitoring is established via delegated and implementing acts. Exploratory discussions on the potential organisation of such future residue monitoring are on-going.

5. TRACES CERTIFICATE – ANIMALS AND PRODUCTS LEAVING FISH FARMS

5.1. Submission by Citizen

Original:

Selon un règlement européen, 1251/2008 le certificat TRACES est exigé même pour les échanges internes aux états membres, au départ de pisciculture indemnes de SHV et NHI.

S'agissant de vente d'oeufs, le certificat certifie rien de plus que le N° d'exploitation agréée, les oeufs n'étant pas suceptibles de "présenter des signes de maladies". C'est juste une paperasse inutile de plus. Il vaudrait mieux exiger des autorités vétérinaires nationales qu'elles aient un fichier centralisé pour vérifier que le N° sanitaire national correspond bien à une pisciculture reconnue indemne au niveau Européen. Et on peut toujours rêver que ce fichier devienne Européen, ainsi plus de certificat TRACES du tout

[3]http://ec.europa.eu/dgs/health_food-safety/pressroom/docs/proposal-regulation-ep-council_en.pdf

http://ec.europa.eu/dgs/health_food-safety/pressroom/docs/official-controls-ia_en.pdf

: en voilà des économies de charges administratives et d'argent public ! Seconde remarque : s'il faut être parfaitement anglophone pour pouvoir avoir son mot à dire sur des règlements européens applicables tels quels dans chacun des états membres, il n'y a pas beaucoup d'Européens qui peuvent avoir leur mot à dire !

Translation:

According to EU Regulation No 1251/2008, a TRACES certificate is required even for internal Member State trade movements starting from fish farms which are free from VHS and IHN.

As regards the sale of eggs, the certificate merely confirms the number of the approved holding as eggs are unlikely to 'show signs of disease'. This is just more needless paperwork. It would be better to require national veterinary authorities to have a central database in order to verify whether the national health number corresponds to a fish farm recognised as disease-free at European level. We can only dream that one day this might become a EU-wide database and we would no longer have TRACES certificates at all: that would really be cutting administrative burdens and saving public money! Secondly, if you have to speak perfect English in order to have your say on EU regulations which are directly applicable in each of the Member States, then not many Europeans would be able to have their say!

5.2. Policy Context

The European legislation on aquatic animal health (Directive 2006/88/EC and Regulation (EC) No 1251/2008) sets out rules for the health certification and traceability of consignments of aquatic animals intended to be placed on the market within the EU. There are two governing principles:

a) aquaculture animals susceptible to, or vectors of, listed diseases, and their products, intended for a Member State, zone or compartment declared free of one or several of those infectious diseases must be accompanied by a health certificate;
b) aquaculture animals susceptible to, or vectors of, listed diseases, and their products, from an area subject to a restriction of movement vis-à-vis one or several of those infectious diseases must be accompanied by a health certificate.

Currently, these requirements must be met by providing appropriate documentation attesting the health status of the holding of origin which must be approved and should accompany the consignment throughout its journey.

In order to simplify this system while maintaining a level of health surveillance enabling rapid response in the event of an outbreak of disease, a notification only is required when animal movements do not require certification. This notification may be made through the TRACES system by the holder themselves without the intervention of the competent authorities.

6. BIOCIDAL PRODUCTS

6.1. Submission by the Austrian Federal Economic Chamber (WKÖ)

A particular provision of the biocides regulation No 528/2012 (article 95) will become relevant on 1. September 2015 and it could become a show-stopper for a large amount of SMEs. This new provision requests from all suppliers of active substances, who want to stay on the market after the mentioned date, to perform an extensive and costly dossier-submission.

It seems that not many companies – in particular SMEs – are aware of the deadline in September. In general, awareness about the recent changes in the area of biocides legislation is very low in the SME sector. Due to intense communication efforts of SME associations it seems that it is not ignorance that causes this lack of information and activity, rather it is caused by the complexity of the biocides regulation and all other heavy pieces of chemical legislation (e.g. REACH and CLP), which are also relevant for a supplier of biocides. Because of that, a fall-back option for all those companies who fail to comply with their obligations on 1 September this year should be established. We suggest a tolerance period of 2 years, in which companies are not fined and can take the necessary action.

6.2. Policy Context

The Biocidal Product Regulation (EU) No 528/2012 aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment.

The Regulation repealed the Biocidal Products Directive (Directive 98/8/EC) and was adopted on 22 May 2012. It became applicable as from 1 September 2013, with a transitional period for certain provisions. The Regulation established a measure in its Article 95 to ensure that only products whose active substance supplier(s) or the product suppliers are on a list established at EU level by the European Chemicals Agency (ECHA) are allowed to be made available on the EU market as from 1 September 2015.

A transitional period of three years has therefore been established in order to provide sufficient time to stakeholders to comply with this measure.

Current state of play

In order to provide specific support to SMEs, specific guidance documents have been developed at EU level by the Commission and ECHA to explain how to comply with this obligation, and to further explain data sharing rules, the negotiation of letter of access to data, and the establishment of consortia (http://echa.europa.eu/regulations/biocidal-products-regulation/approved-suppliers, http://echa.europa.eu/practical-guides/bpr-practical-guides).

7. TRADITIONAL HERBAL MEDICINES

7.1. Submission by Citizen

Burden on business

The Traditional Herbal Medicinal product directive is not fit for purpose. I am a regulatory compliance consultant and to date I have told 100s companies they cannot market their botanical/herbal products in the EU, because they are not foods, but do not fit into the extremely narrow definition of traditional use: 30 years on the market, 15 of which in EU. Firstly, traditional use is a term used in herbal medicine and means exactly that. Whereas the THMPD means market data on identical formulas of the same indication, the term traditional use should be changed to market evidence. This law more than any other has stopped innovation and plain prevented many good products from being available to consumers. Another problem is that botanical health claims have been put on hold by the European Food Standards Agency (EFSA) for seven years. The botanical food and herbal medicines market has been unduly prevented from decent business by European law and there is no reasonable justification for this. I have compliance reviewed literally 1000s of natural health care products for the EU market, so this is a genuine problem observed through practice.

Suggestion for simplification

Revise the THMPD to allow for a genuine definition of traditional use. Get EFSA to do their work on Botanicals rather than just putting things on hold for years and years. There is no excuse for this and the motivation behind these directives and why EFSA have put botanicals on hold for so many years is entirely unclear.

7.2. Policy Context

The herbal products referred to in the suggestion can be marketed either as food or as pharmaceutical product depending on the circumstances. The suggestion therefore refers to two legislative texts dealing on the one hand with **botanicals falling under the food law** and on the other hand with **herbal medicines falling under the pharmaceutical legislation**.

Health claims made on botanicals marketed as **food** are covered by Regulation (EC) No 1924/2006 on nutrition and health claims. This Regulation was adopted in 2006 to govern the use of these claims in the labelling, presentation and advertising of foods. It aimed in particular at enabling consumers to make healthier choices by protecting them from misleading information and ensuring a level playing field for food business operators within the internal market. The scientific assessment of health claims is performed by the European Food Safety authority (EFSA).

EU legislation on pharmaceutical products for human use also applies in general to traditional herbal medicines. However, in order to overcome difficulties encountered by Member States in applying pharmaceutical legislation to **traditional herbal medicinal products** in a uniform manner, a simplified registration procedure was introduced in 2004 as an exception to the general requirement for marketing authorisation in the EU.

The simplified procedure was introduced by Directive 2004/24/EC of the European

Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC (THMPD) on the Community code relating to medicinal products for human use.

Herbal medicinal products are defined as any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.

This simplified registration procedure is intended for herbal medicinal products with a long tradition, which do not fulfil the requirements for a marketing authorisation, in particular those requirements whereby an applicant can demonstrate by detailed references to published scientific literature that the constituent or the constituents of the medicinal products has or have a well-established medicinal use with recognised efficacy and level of safety (so-called "well established use").

The simplified procedure allows the registration of herbal medicinal products without requiring particulars and documents on tests and trials on safety and efficacy, provided that there is sufficient evidence of the medicinal use of the product throughout a period of at least 30 years, including at least 15 years in the Union. This latter requirement ensures that the simplified registration is applicable to herbal medicinal products with a Union tradition.

With regard to the manufacturing of these products and their quality, applications for registration of traditional herbal medicinal products have to fulfil the same requirements as applications for a marketing authorisation.

Directive 2004/24/EC had to be implemented by October 2005. However, a long transitional period of 7 years was granted to register traditional herbal medicinal products that were already on the market on the date of entry into force of that Directive. The transitional period ended on 30 April 2011.

Current state of play

Health claims on herbal food products

In the context of the implementation of the Regulation on health claims, more than 500 claims on plants and their preparations (botanicals) received an unfavourable assessment from EFSA in the context of their scientific assessments, and this raised many concerns among Member States and many stakeholders regarding health claims made on plants and their preparations used in food. To date, the remaining over 1500 submissions concerning such health claims have not yet undergone the scientific evaluation by EFSA.

The Regulation provides that all health claims, including those on plants and their preparations used in food, should be assessed on the basis of scientific evidence at *'the highest possible standard'*. In this context, EFSA considers human studies as essential for the substantiation of claims. Hence, EFSA considered that evidence collected on the basis of experience gained over time with the actual consumption of the plants and preparations *(‘traditional use'*) alone cannot be considered sufficient to allow for the scientific substantiation of a health claim made on foods.

Under the current EU rules, it is possible for a Member State on a case-by-case basis to classify a product as food or as medicine depending on its presentation and claimed effect. Therefore it is possible that differences exist between Member States in the

classification of products. In other words, as EU law stands, it is possible that the same product is classified as a foodstuff in one Member State and as a medicinal product in another.

Pending further action to regulate health claims on plants and their preparations, health claims made on such substances and which were submitted in the context of the establishment of the list of permitted health claims, may still be used pursuant to the transitional periods foreseen in Article 28(5) of the Regulation which requires that health claims comply with the Regulation and with the existing national provisions applicable to them. It is therefore difficult to understand the claim that "the botanical food and herbal medicines market has been unduly prevented from decent business by European law", as far as claims on botanical food supplements are concerned. On the contrary, claims on botanical food supplements benefit from a longer transition period compared with other health claims.

The Commission is evaluating the Regulation in particular in view of the issue raised by this contribution and the roadmap for this REFIT evaluation is available at http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_595_evaluation_health_claims_en.pdf

Simplified authorisation procedure for traditional herbal medicinal products

In September 2008, the report on the experience with the registration of the traditional herbal medicinal products required by Article 16 of Directive 2001/83/EC was finalised. At the time of the report limited experience had been gained with only 110 applications for registrations submitted to the National Competent Authorities and finalisation of 23 applications. Now (until December 2014), almost 2500 applications for registration have been received and more than 1400 traditional use registrations granted.

8. REGISTRATION OF FEED BUSINESS OPERATORS

8.1. Submission by the Finnish Survey for better regulation

Under the Regulation laying down requirements for feed hygiene (EC) No 183/2005, a retailer making available plant-based products for feeding animals kept for food production must be registered as a feed business establishment. Finland is exploring the possibility of waiving the obligation to register as a feed business establishment for certain operators and functions.

8.2. Policy Context

The objective of Regulation (EC) No 183/2005 is to ensure a high level of consumer protection with regard to food and feed safety. Central to this regulation are two guiding principles, which may be summarised as follows:

1. Primary responsibility for feed safety rests with the feed business operator. The onus of providing safe food lies with all individuals responsible for producing that food. For the purposes of this regulation feed business operators include: farmers at all stages of the production chain (such as tillage or livestock farmers), manufacturers of compound feed, hauliers of feed, importers of feed and individuals involved in the sale and distribution of

feed to farmers.

2. The need to ensure feed safety throughout the feed chain, starting with primary production of feed, up to and including the feeding of food producing animals. Primary production of feed includes all tillage and grassland production, food producing animals include for example beef animals, beef and dairy cows, sheep, pigs, poultry, horses, goats, deer, ostrich, and fish, etc.

Unless specifically excluded from the scope of Regulation (EC) No 183/2005, any establishment selling feed must be registered as a feed business establishment with their local authority.

Current state of play

Several Member States requested a revision of the scope of Regulation (EC) No 183/2005, applicable since 1 January 2006, with the purpose to exclude certain retailers (retailers distributing "hobby feed", meant as feed intended for food producing animals kept in private households and intended exclusively for private consumption) in order to offer more flexibility to small enterprises.

The Commission will consider a proportionate solution for the issue raised by the Finnish Survey for better regulation.

9. TRANSPORT OF DOGS BETWEEN MEMBER STATES

9.1. Submission by Citizen

Transport regulations for greyhounds from Ireland to mainland UK. Transporters are required to have Baili Certs travelling from the republic but not from Northern Ireland causing a competition anomaly and a barrier to trade. We seek derogation on the basis that both islands are considered an epidemiological unit and precedence has been set by the thorough bred industry.

9.2. Policy Context

The dispatch of dogs, including greyhounds, from one Member State to another is governed by the animal health conditions laid down in Council Directive 92/65/EEC and subject to the veterinary checks applicable to such trade in accordance with Council Directive 90/425/EEC. They are therefore applicable between to greyhounds moved between the Republic of Ireland and Northern Ireland or mainland UK.

Those two Directives do not apply to the movement of dogs on the territory of a Member State, even if this territory is not contiguous. Therefore, the movement of greyhounds from Northern Ireland to Great Britain is not affected by Union rules but may have to comply with the relevant national rules in force in the United Kingdom, such as marking requirements.

The specific animal health conditions for the movement of certain registered horses

between France, Ireland and the UK, the so-called Tripartite Agreement, is based on Article 6 of Directive 2009/156/EC, which allows Member States implementing an alternative control system providing equivalent guarantees as regards movements within their territory of equidae, to grant certain derogations from the provisions of that Directive on a reciprocal basis.

Such legal base for a derogation from applicable animal health conditions does not exist in Directive 92/65/EEC as regards intra-Union trade in dogs, except for dogs which are less than 12 weeks old and have not received an anti-rabies vaccination, or are between 12 or 16 weeks old and have received an anti-rabies vaccination but do not meet the validity requirements for anti-rabies vaccinations. This derogation remains at the discretion of Member States.

10. MEDICINAL PRODUCTS FOR HUMAN USE

10.1. Submission by the Finnish Survey for better regulation

The directive relating to medicinal products for human use (2001/83/EC) should be re-issued as a regulation like the proposal for medicinal products for animal use. This would reduce the administrative burden; lower costs; harmonise legislation; narrow down legal interpretations; facilitate the adoption of amendments; and improve the operation of the internal market.

10.2. Policy Context

Directive 2001/83/EC (the medicinal product directive) governs the national authorisation procedures for human medicinal products, as well as the rules for the constant supervision of products after their authorisation. Additionally, it includes rules regarding the manufacturing, the distribution and the advertisement of medicinal products.

The Directive is part of a broader EU acquis for human medicinal products.

Since its adoption in 2001, the Directive has been subject to frequent changes (12 amendments) in order to ensure that it remains fit for purpose by adapting it to scientific developments and new regulatory concepts, e.g. decentralised procedure for authorisation (2004), pharmacovigilance review (2010/2012), protection of supply chain against falsified product (2011).

While implementation at Member State level is sometimes delayed, there is currently no pending infringement case against Member States.