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stances, the differences in attitudes among Member States and the need to protect health as a priority make the role of the Court an essential tool in a living and lively law system.

ABSTRACT

Shall Article 1(2)(c) of Regulation (EC) No 258/97 be interpreted as meaning that the expression 'new primary molecular structure' relates to foods or food ingredients which were not used for human consumption in the territory of the EU before 15 May 1997, or to those whose molecular structure did not exist as such in nature before that date? In case C-448/14, the EU Court opts for the first solution, thus including in the scope of the Novel Food Regulation also substances of mineral origin. This short note comments on the judgment, with an approach that, though critical, ends up in sharing the Court's findings.

L'articolo 1, paragrafo 2, lettera c del Regolamento (CE) n. 258/97 deve essere interpretato nel senso che l'espressione "struttura molecolare primaria nuova" si riferisce ad alimenti o ingredienti alimentari che non erano usati per il consumo umano nel territorio dell'Unione europea prima del 15 Maggio 1997, o a quegli alimenti o ingredienti la cui struttura molecolare non esisteva in natura prima di quella data? Nella causa C-448/14, la Corte UE adotta la prima soluzione, includendo così, nel campo di applicazione del Regolamento sui Novel Foods, anche le sostanze di origine minerale. Questa breve nota offre un commento alla sentenza, con un approccio che, pur se critico, finisce con il condividere il risultato cui è giunta la Corte.

Concurring opinion

Bernd van der Meulen

In the EU, food may not be placed on the market if it is unsafe (Article 14 of Regulation (EC) No 178/2002). A food may be unsafe due to its condition (contamination, decay, etcetera). It may also be unsafe due to its inherent characteristics. For conventional foods their inherent safety is assumed on the basis of experience. Over the twentieth century, legislators have increasingly designated categories of foods with regard to which they replaced the assumption of safety by a requirement to provide evidence of safety in an authorisation procedure. The system is that all foods fulfilling the definition of the designated category are banned from the market. This ban can be lifted by an authorisation. This authorisation usually takes the shape of inclusion of the product at issue in a positive list. In 1967 E.J. Bigwood and A. Gérard started a research series on Fundamental Principles and Objectives of a Comparative Food Law[1]. They present as core elements of structure the Principle of Abuse and the Principle of Prohibition. The former allows the production, sale and use of any food not expressly prohibited or marked on a negative list of unauthorised products. The principle of prohibition by contrast entails a general prohibition of anything not included in a positive list of authorised products, a list established and kept up to date by public authorities (p. 37). In practice countries use mixed systems applying prohibition only to foreign substances.

In the USA the prohibition principle has been introduced in 1958. Congress has chosen to apply the prohibition with authorisation requirement to the widest imaginable group of foods: 'anything added to food' (in American nomenclature these are food

(1) Bigwood É.J. - Gérard A., *Fundamental Principles and Objectives of a Comparative Food Law*, Karger, Basel-New York, 1967.

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additives). The EU by contrast has chosen a very different approach from the very beginning. Rather than requiring pre-market assessment of 'anything' the EU only brought well-defined categories of foods under such requirement (for example colouring matter in 1962 Directive 62/2645/EEC; preservatives, in 1964 Directive 64/54/EEC; antioxidants in 1970 Directive 70/357/EEC; food additives in general Directive 89/107/EEC; food supplements in Directive 2002/46/EC; GMOs in Regulation (EC) No 1829/2003).

The Novel Foods Regulation can indeed be understood as a departure from the product-category-by-product-category-approach by placing an umbrella over all the authorisation requirements covering all (other) foods not having a history of use. In fact I have advocated such reading myself[2]. In this reading, the listing of categories should not be understood as a delineation of the scope of the regulation, but rather as an attempt of the legislature to list all imaginable new foods. The obvious counter argument is that if this is what the legislature wanted, they would have followed the American approach which requires the authorisation of 'anything' rather than a listing. Indeed in listings not intended as limiting, usually an umbrella category 'any other' is included. See for example Article 2, No 4 of the Official Controls Regulation[3], listing enforcement powers.

It goes without saying that safety assessment of 'anything' is humanly impossible. Indeed we see that despite all protestations regarding supporting innovation, with the introduction of the Novel Foods Regulation all innovation at the level of food materials has come to a virtual standstill. Despite the fact that globally some 6.000 plant species[4] and 2.000 insect species[5] are consumed by humans that would classify as novel foods in the EU; despite the urgent need to broaden the EU's agro-biodiversity in the face of climate change,[6] the total number of foods authorised under the Novel Foods Regulation is less than 2 per year for the twenty years it has now been in force, less than 2 per Member State for the 28 States that are now members of the EU.

For the system to work it is vital the *de minimis* innovations are excluded for the scope of the Novel Foods Regulation. In the USA the consequence of the over-broad scope of the authorisation requirement is dealt with by excluding all substances that do not raise any concern because they are considered by experts qualified to make such assessment as GRAS (i.e. generally recognized as safe).

In EU food law, we do not find a general *de minimis* clause like the GRAS-exemption. We do, however, find some *de minimis* exceptions for example in category (e) (of Article 1(2) of the Novel Foods Regulation) "foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals". From this category exempted are "foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use". By consequence, the innovations that are achieved on a daily basis in plant and animal breeding are exempted from safety assessment and authorisation. Horticulturists and farmers have been cross-breeding species for so long, that the legislator trusts the outcome of such practices without a need for prior assessment.

In food additives we see processing aids excluded from the scope of the authorisation requirement. Processing aids are additive-like substances that are added to the process to perform a technological function. They or their residues may still be present in the final product, but they escape the authorisa-

(2) Van der Meulen B. - Van der Velde M., *European Food Law Handbook*, Wageningen Academic Publishers, 2008, pp. 292-293.
(3) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. See also Article 3 (3)(b) of Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.
(4) Knudsen I. et al., *Risk management and risk assessment of novel plant foods: concepts and principles*, in *Food Chem Toxicol*, 2008, 46, 5, pp. 1681.
(5) Van Huis et al., *Edible insects. Future prospects for food and feed security*, FAO, Rome 2013, p. xiii.
(6) See for example: JRC, *Delivering on EU Food Safety and Nutrition in 2050 - Future challenges and policy preparedness*, 2017, available at https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/delivering-eu-food-safety-and-nutrition-2050-future-challenges-and-policy-preparedness [07.09.2017].

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tion requirement if they perform no function in that final product, provided that they are safe. Food businesses are responsible that this safety requirement is met, but they are not required to submit any evidence to any authority. Indeed a prior authorisation scheme for processing aids in France was considered by the Court to constitute an unjustified barrier to trade as long as prior risk assessment by France did not show evidence of risk[7].

In the same way the category (c) in Article 1(2) of the Novel Foods Regulation "foods and food ingredients with a new or intentionally modified primary molecular structure" can be understood as exempting *de minimis* from the scope. Shockingly, the Court does not stop to reflect what the concept "primary molecular structure" means. Indeed the learned judges seem to assume – as probably only a lawyer can do – that reference is made to anything consisting of molecules. The concept "primary molecular structure" comes from structural biology. In this branch of molecular biology, it is used exclusively in relation to proteins.[8] Other substances are not usually considered having a "primary molecular structure". More specifically does the concept relate to the sequence of amino acids. Biochemistry then goes on to distinguish secondary, tertiary and quaternary structures. In biochemistry category (c) would be understood to exclude from the scope of the Novel Foods Regulation all alterations of proteins limited to the secondary, tertiary or quaternary structure and not affecting the primary structure.

The reading of the provision by the Court is dramatically different. It does not see the category as exempting, but it extends the scope of the authorisation requirements of the Novel Foods Regulation from major changes in the molecular structure of proteins to all changes in the molecular structure of proteins, to all changes in the molecular structure of any substance, indeed to the introduction of any substance consisting of molecules.

With this ruling, EU food law has reached an extreme point in application of the prohibition principle. Any molecule, indeed any arrangement of molecules, that was not consumed to a significant degree in the EU prior to 1997 is subject to authorisation (with the sole exception of new varieties of plants or animal obtained by traditional methods of breeding). What is needed now is a serious de minimis exception. Depending on how it will be applied in practice, the lighter procedure of exotic novel foods in the new Novel Foods Regulation, may be a relevant first step in that direction.

ABSTRACT

Judgement in case C-448/14 proves to be the EU food law extreme point in application of the principle of prohibition which entails a general prohibition of anything not included in a positive list of authorised products, a list established and kept up to date by public authorities.

Unlikely the biochemistry concept of "primary molecular structure", the Court does not see the category as exempting, but it extends the scope of the authorisation requirements of the Novel Foods Regulation from major changes in the molecular structure of proteins to all changes in the molecular structure of proteins, to all changes in the molecular structure of any substance, indeed to the introduction of any substance consisting of molecules.

However, for the system to work, it would be vital to exclude the de minimis innovations from the scope of the Novel Foods Regulation, similarly to the USA GRAS exemption.

□

([7]) Judgment of the Court (Third Chamber) of 28 January 2010, European Commission v French Republic, Case C-333/08. On this case, see: van der Meulen B.M.J., *Prior authorisation schemes: trade barriers in need of scientific justification, Case C-333/08 Commission v. French Republic 'processing aids'*, in *European Journal of Risk Regulation*,1, 4, pp. 465-471.

([8]) See for example Cachapa Rodrigues I., in Van der Meulen B. (ed.), *Reconciling food law to competitiveness. Report on the regulatory environment of the European food and dairy sector*, Wageningen Academic Publishers, 2009, p. 109. However, even Wikipedia provides this information. Some googling, therefore, would have provided the Court all the required background information.