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"New primary molecular structure" and novel foods according to the Court: constructive or demolishing interpretation?
The EU Court Judgment in case C-448/14*

Valeria Paganizza

1.- Introduction

Either greeting the EU Court's finding in C-448/14[1] as the needed interpretation of Regulation (EC) No 258/97[2] or regarding it as a subverting reading on legal certainty might be just a question of hermeneutics[3].
As the Reader might know, Regulation (EC) No 258/97 sets two requirements – that have to coexist - to include a product in the definition of novel food. The first one is a time condition: the substance or ingredient had not been "significantly" used as food before 15 May 1997.
The second one is a class requirement: the product has to fall into one of the categories listed in the Regulation, refined over years, namely «*foods and food ingredients with a new or intentionally modified primary molecular structure*»; «*foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae*»; «*foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use*»; «*foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances*» (Article 1, paragraph 2 of Regulation (EC) No 258/97).
What if a substance or ingredient does not match or does not perfectly fit any of the groups? Shall we interpret the Regulation according to its wording, or shall we pay attention to the general *ratio*, trying to understand the legislative intent? Can we fill any gaps through an extensive interpretation? And could we make use of "by analogy reasoning"? Can we apply the general principles of the theory of interpretation to EU law, or has the Court identified different and autonomous methods to provide a meaning?
Answers to such questions are in the judgment in case C-448/14. The Court's finding is however so plain and apparent that some scholars could struggle to accept it without arguing. And this is the reason why the Author wrote this note.

2.- The case

Davitas Gmbh is a German company of the food and food supplement sector. Since 2012, it had been marketing, in Germany, a food product (called De Tox Forte) made solely of a mineral (clinoptilolite), which had never been used for human nutritional purposes within the EU. After an official control on the product composition carried out by experts, and grounding its measure on the fact that the use of clinoptilolite as food had never been significant, the municipality of Aschaffenburg prohibited the marketing of the product, until Davitas would have obtained an authorisation under the Novel Food Regulation. Davitas however argued that its product was not a "novel food", under the denotation given in the Regulation and brought an action for annulment before the Bavarian Administrative Court,

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(1) Judgment of the Court (Fifth Chamber) of 9 November 2016, *Davitas GmbH v Stadt Aschaffenburg*, Case C-448/14.
(2) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

rivista di diritto alimentare
www.rivistadirittoalimentare.it
Anno XI, numero 3 · Luglio-Settembre 2017

Würzburg (Bayerisches Verwaltungsgericht Würzburg), against the authority's ban.
After the rejection, Davitas appealed the judgment to the Higher Administrative Court of Bavaria (Bayerischer Verwaltungsgerichtshof). Though recognising that clinoptilolite had not been used as food significantly, within the EU, the appellant specified that it did not fall into one of the categories listed in Regulation (EC) No 258/97. Lacking therefore the second condition, the product could not be considered a novel food. In particular, Davitas specified that De Tox Forte could not fall into the category of food with a "new primary molecular structure", since its structure was the same as the one of the volcanic zeolite.
Staying the proceedings, the appellate Court, which raised some interpretative doubts on the scope of Regulation, referred two questions to the EU Court: «*1. Is the product "De Tox Forte" marketed by the appellant a food or food ingredient with a new molecular structure within the meaning of Article 1(2)(c) of Regulation No 258/97?*
2. In particular, does it suffice, in order to be able to answer this question in the affirmative, that that product, which contains the substance clinoptilolite in its particular primary molecular structure, was not yet being used as a food prior to 15 May 1997, or is it also necessary that that product is produced by means of a production process which results in a new or intentionally modified molecular structure, that is, it must be a substance which did not previously exist in nature in that form?» (point 15 of the judgment).

3.- General Advocate Opinion

A careful reading of the Opinion of Advocate General Szpunar might be functional to fully understand the judgment of the Court and its reasoning. He summarises the two questions in a single query, namely whether the category of food with a new primary molecular structure includes a substance of mineral origin having the same structure as in nature, though that structure had not been used in food or food ingredients before 15 May 1997 (point 18 of the Opinion). To answer the question, he carries on a legal reasoning that we could abridge in few points:
-Inadequacy of the literal interpretation to solve the issue;
- Possible conceptual overlapping of the conditions to qualify a food as novel, and acceptability;
- Comparison with the new EU provisions on novel foods;
- Interpretation under the general nature and purpose of the novel food Regulation;
- Historical reading;
- Reading according to practice.
Recalling some principles of EU law hermeneutics, the Advocate General suggests that the interpreter of an EU act shall not consider just the wording, but has to regard also at its context and the «*objectives pursued by the rules of which it is part*» (point 20 of the Opinion). Trying to reach a solution through the meaning of the adjective "new", the EU Officer recognises that it can refer to both a molecular structure that had been newly created and a newly used one, in food. He then draws a remarkable reasoning over the overlapping of concepts. Thinking to a "new molecular structure" as something that has not been used before as food, would superfluously replicate the first criterion that a substance has to match, to be a novel food. According to the Advocate General however such overlapping would occur only for those substances that cannot find a classification within the other categories listed in the Regulation and that could be identified in substances of mineral origin. To support his interpretation, the EU officer refers to the new regulation on novel foods that expressly includes food of mineral origin within its scope.
The main point of the Opinion concerns indeed the scope of the novel food regulation and the assertion that the general nature and purpose of the definition of novel food prevent a restrictive interpretation (point 41). The general nature – according to the Opinion – is due to the fact that the regulation covers all novel foods «*irrespective of their nature, with the exception of certain areas which are regulated by sector-specific legislation*».
The purpose consists in defining the characteristics to categorize a food as novel, with the objective of ensuring the functioning of the internal market, while protecting consumers' health. So plants, fungi, algae and microorganisms are novel foods regard-

rivista di diritto alimentare
www.rivistadirittoalimentare.it
Anno XI, numero 3 · Luglio-Settembre 2017

less of whether they are the results of human intervention, in order to protect human health. Similarly, according to the Advocate General, also food with a new primary molecular structure shall be novel food, irrespective of whether the structure is newly created or newly used within the European Union (points 43-44 of the Opinion).
Moreover, only letter c) of the Regulation could include substances of mineral origin that have not undergone a new production process giving rise to significant changes in their composition and structure.
The exclusion of an entire category of food (substances of mineral origin), that would happen through a restrictive interpretation of the Regulation, would «be contrary» to the general scope and purpose of the EU act.
As for the historical development of the wording, the Advocate General's reasoning does not give much importance to the difference between the Commission proposal - clearly including, in the Regulation, food with a primary molecular structure that had not been used before - and the text released after the Council's Common Position, where the sentence was not retained. He simply asserts that the lack in the final version of the Regulation does not necessarily mean that the Legislator intended to exclude the category from the scope of the act.
Finally, the Advocate General underlines that prior to the Davitas case, within the European Union, clinoptilolite had already been qualified as "novel food" in "practice": it was included in the EU online Novel Food Catalogue and food business operators had considered it as "novel food" while submitting applications for trade authorisation.

4.- Decision and motivation

In accordance with the Opinion of the Advocate General, the Court of Justice includes in the category of food with a new molecular structure also substances of mineral origin, considering "new" any structure that had not been used within the European Community before 1997, regardless of whether it had been newly created or just newly used.
To answer the referred questions, the Court makes use of hermeneutics topics too. We could summarise the reasoning into the following points:
- Summing-up of the questions with a focus on the meaning of "new primary molecular structure";
- Regulation (EC) No 258/97, subject and scope (the coexistence of the two conditions to classify a food as "novel");
- Comparison between the general wording of letter (c) and the detailed provisions of letters (d), (e) and (f) of paragraph 2, Article 1 of Regulation (EC) No 258/97;
- Fundamentals of EU law hermeneutics: usual meaning, context, purpose and their application to the case.
Similarly to Advocate General's reasoning, the Court starts its analysis from turning the referred questions into a single query on the meaning of "new primary molecular structure", wondering if it includes simply substances that had not been consumed significantly as food prior to 15 May 1997 (regardless of whether the structure had already been existing in nature) or if it requires also the novelty of the form, meaning that the substance underwent a process that resulted in a new or intentionally modified structure.
The EU Judge then focuses on the subject of Regulation (EC) No 258/97 (that it identifies in the placing in the market of novel food or food ingredients), and recognises that the definition of "novel food" determines by itself the scope of the Act. The Court recalls therefore the two conditions that the classification as novel food requires to this purpose, namely the use as food prior to 15 May 1997 and the referability to one of the categories listed in Article 1, paragraph 2 of the Regulation. It then analyses the content of such classes, paying particular attention to substances "with a new primary molecular structure" - the category mentioned in the referred questions - and emphasising its peculiar wording. While this class makes a general reference to the structure of a food or food ingredient, letters d), e), and f) of Article 1, paragraph 2 show more detailed provisions, the first two concerning organic substances having a particular composition and the last one encompassing food which underwent a new production process resulting in a significant change in its composition and structure.
The Court carries on its reasoning through a herme-

rivista di diritto alimentare
www.rivistadirittoalimentare.it
Anno XI, numero 3 · Luglio-Settembre 2017

neutical approach, wondering if "new molecular structure" refers only to structures that have been newly created, or simply to any substances with a structure that has not been used before as food. The usual meaning of words being insufficient to provide an unambiguous interpretation, the EU Judge perceives the need for considering the context in which the phrase is used and the purpose of the Regulation.
Although formally referring to the context, actually the Court focuses on the scope of the Act, emphasising its general nature and stating that it covers "*all novel foods or food ingredients irrespective of their nature, with the exception of certain areas regulated by sector-specific legislation*" [point 29]. On this basis, it interprets Article 1, paragraph 2, letter c) of the Regulation as referred to any substances that had not been used significantly as food prior to 15 May 1997.
The reason for such reading is the need not to exclude substances that would not otherwise fall into any of the other categories listed in the Regulation.
Also the reflection on the purpose of the novel food provisions would bring about the same result: since the Regulation aims to ensure free movement of goods, while protecting human health, a comprehensive safeguard would require the authorisation procedure set for novel foods, for any substances that had not been significantly used as food until May 1997.

5.- Comment

If we make reference to the purpose of the Regulation[3], the need to protect human health might justify the Court's findings. When a substance has not been used as food, it shall undergo a risk assessment procedure in order to evaluate its suitability and safety for human consumption.
Indeed, this is a general recurrent approach in EU Food Law, where anything that is unknown to nutrition must be assessed in order to ascertain its safety. Sometimes EU provisions require a technical independent evaluation carried out by national authorities or through EFSA intervention: this is the case of GMOs food additives, but also novel foods authorisations. For these categories, the EU regulations ask the completion of a procedure prior to the marketing of the products. Where the food belonging to this group has not undergone or has failed to pass the evaluation process, it will be considered unsafe. Such unsafety does not perfectly match what Article 14 of Regulation (EC) No 178/2002 identifies as "unsafe", that is to say a food injurious to health or a food unfit for human consumption. Abstractly a food that has not undergone an authorisation procedure might be absolutely innocuous. It might however be considered unfit for consumption, just because of the lack of the formal requirement (the successful completion of the authorisation procedure).
The unsafety of a food that has not obtained the authorisation might be inferred also through Article 14, paragraph 7, which states that «Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned».
This could be read also in the opposite: food that does not comply with specific Community provisions governing food safety shall be deemed to be unsafe.
Sometimes food business operators carry out just a self-assessment and do not have to submit any request, for instance when they simply perfect a new recipe: the product final composition is something new, while its ingredients are substances already used for human nutrition.
Even though abstractly such ingredients could interact, the safety of their use is alleged and ensured by the operator, who, under Regulation (EC) No 178/2002, has a general duty to put on the market

([3]) Several Italian Authors commented on the "old" novel food regulation, though focusing mostly on GMOs; see Germanò A., *Sui novel foods*, in *Dir. giur. agr. alim. amb.*, 2009, 9, pp. 534-535; Masini S., *Coltivazione di organismi geneticamente modificati: esigenze di sicurezza e presunzione di responsabilità*, in *Dir. giur. agr. amb.*, 2000, 11, pp. 637-644; Costato L., *Organismi biologicamente modificati e novel foods*, in *Riv. dir. agr.*, 1997, 2, I, pp. 137-164.

rivista di diritto alimentare
www.rivistadirittoalimentare.it
Anno XI, numero 3 · Luglio-Settembre 2017

only safe products[4].

The logical reasoning of the Court might however be questionable. It is undeniable that the wording of the Novel Food Regulation on substances with a "new primary molecular structure" cannot help in solving the question on the applicability to materials of mineral origin.

However we could draw several considerations, giving a hint about different perspectives. The purpose of the provisions on Novel Food is to regulate the access to the EU market of substances that have not been consumed significantly as food, in order to ensure their safety. Requiring an authorisation prior to the market is however an exception to the general principle of free movement of goods. With these elements in mind, the EC Legislator established a precise set of rules for novel foods (and only for them), thus reducing as much as possible the limitations to the free movement of goods. When focusing on the context of the Regulation, the Court states that it has a general nature, since it applies to any novel food or food ingredient, except for those products that fall into a different specific discipline (for instance, additives). The assertion of the EU Judge is accurate but it seems to disregard the fact that the definition of "novel food" comes from the Regulation itself.

As underlined in the Court's Judgment, the Regulation identifies two conditions that a food ingredient has to match to be qualified as "novel". Nevertheless, the EU Judge breaks down the structure of the act, by its interpretation of the phrase "new primary molecular structure". To the question if the expression means "any molecular structure that did not exist previously" or "any molecular structure that was not used in or as food", the Court concludes that the wording encompasses simply any substance that had not been significantly consumed as food prior to May 1997. But in doing so, the EU Judge de facto nullifies the meaning of the second condition laid down in Article 1, paragraph 2, letter c) of the Regulation, through a worthless duplication of the first condition. What is more is that such hermeneutical operation turns out to abolish entirely the need for and sense of a second condition, or at least it risks doing so. The Court reads "new primary molecular structure" as including any substances that cannot otherwise fall into any of the other categories. Sure, the Judge reasons only with regards to "clinoptilolite" and "substances of mineral origin", but the hermeneutical process is something that could be replicated for any product that cannot be assigned to the other listed categories. According to the Court's reasoning, "new primary molecular structure" becomes a residual class that could be able to cover almost any gaps in novel food categories.

There is something disturbing in this perception. If the EC Legislator had wished that any food or food ingredients that had not been used as food prior to May 1997 would be considered as "novel food", it would not have required the matching of a second condition and it would not have listed a specific set of classes. It would have simply stated that any substances that had not been used prior to 1997 as or in food should have been considered a "novel food" and should have undergone the authorisation procedure. The EC Legislator made instead something different: it considered novel food any substance that had not been significantly consumed as food prior to that moment, *provided that* it fell into one of the listed categories. We could guess that it had some reasons to do that. We could also imagine that technical developments suggested that the wording of the Regulation had to change. Indeed the new Regulation (EU) 2015/2283[5] includes also

([4]) Actually, also such certainty might falter when reading the EU Court's judgment of 15 January 2009, in case C-383/07, *M-K Europa GmbH & Co. KG v Stadt Regensburg*, according to which the fact that a food or all the individual ingredients of a food had been singularly consumed to a significant degree before 15 May 1997 is not sufficient for the Regulation (EC) No 258/97 not to apply to the food product concerned (points 30-32).

([5]) Several Authors commented on the new regulation. *Ex plurimis*, Canfora I., *Alimenti, nuovi alimenti e alimenti tradizionali nel mercato dell'Unione europea dopo il regolamento 2015/2283*, in *Diritto agroalimentare*, 2016, 1, pp. 29-46. In this review, Bonora G., *I "Novel Foods" nel Reg. (UE) n. 2015/2283 e gli insetti: una possibile evoluzione dei costumi alimentari?*, www.rivistadirittoalimentare.it, 1-2016, pp. 42-54; Volpato A., *La riforma del regolamento sui "Novel Foods": alla ricerca di un impossibile equilibrio?*, www.rivistadirittoalimentare.it, 4-2015, pp. 26-43.

rivista di diritto alimentare
www.rivistadirittoalimentare.it
Anno XI, numero 3 · Luglio-Settembre 2017

"*food consisting of, isolated from or produced from material of mineral origin*". However this does not necessarily imply – unlikely what the Advocate General argues – that the inclusion of substances of mineral origin in the new Regulation on novel foods means that also the old novel food regulation was intended to cover such substances.

Though the new Regulation declares that its scope should, in principle, remain the same as the repealed one, it also specifies that the definition of novel food needs a review, clarification and an update, "*on the basis of scientific and technological developments that have occurred since 1997*" (Whereas no 8). So we can infer that the new Regulation includes anything that was Novel Food under the last consolidated version of the previous Regulation but adds some new categories, thus clarifying also its scope. In this sense, the scope of the old regulation has survived the act, but we cannot obviously uphold the reciprocal statement, unlikely what the Advocate General did.

We cannot in other words say that the old regulation already included all that the new act describes as Novel Food. This would be irrational: the intention of the EC Legislator of 1997 could not foresee what the EU Legislator in 2015 would have done. Though not expressly mentioned in the judgment, the EU Court might have considered also this point of the Advocate General's Opinion.

The Court has however a clear and declared purpose: requiring the authorisation procedure for any substances that had not been used as food, prior to May 1997, despite the structure and the wording of the Regulation.

What is alarming in such point is that the EU Judge operates an extension of what should be considered an exception. One of the fundamentals of the European Union is the free movement of goods. The fact that the European Community (now Union) has established some restrictive rules is a peculiarity due to a specific reason (ensuring the need to protect human health, without unnecessarily limiting trade opportunities), turning to be an exception to the general freedom. The exclusion is furthermore circumstantial, being restricted to specific categories of products.

The Court's hermeneutical process cuts down these classes and seems to include in the residual one (new primary molecular structure) any substances that do not fall into other categories, for the sole reason that they would otherwise enter the EU market without a prior authorisation. To be intellectually honest, we should advice that the Author of the paper is offering a radical reading of the judgment. Someone could indeed successfully argue that this is not an automatism applicable to any substances: it would work only for those products having a new primary (and not secondary) molecular structure that – as in case of substances of mineral origin – replicates an undefined number of times. Let's think to insects. Article 1, paragraph 2 of Regulation (EC) No 258/97, letter e) includes, in the definition of novel food, "food ingredients isolated from animals", but not food or food ingredients consisting of animals. Some EU members interpreted such expression in the sense of excluding whole insects from the scope of the Regulation, while including parts of or substances extracted from these animals. According to the reading of the Court, probably whole insects would still remain outside the scope of the EC act.

The category listed in the Regulation refers to a primary molecular structure, while insects – as many other organisms - have a complex molecular structure. Should we try to identify the primary one, we will probably find several "groups" of molecular structures (for carbohydrates, for fats, for proteins or amino acids, for minerals, besides water and chitin)[6]. Moreover, should we focus on those groups, probably we will realize that they have already been used as food and this would turn to be a tricky element. We know that the old novel food regulation did not expressly include insects within its scope. If we focus on their structure, we should conclude that their primary constituents have already been part of the EU consumers' diet for centuries and therefore

([6]) A special thanks goes to dr. Sara Bortolini, University of Modena and Reggio Emilia, who explained to the Author, with a precise and thorough description, what the composition of insects is. Here there is an attempt to summarise in few everyday words the main points of her helpful speech.

there would not be any reason leading to their inclusion in novel foods[7]. However, the new regulation declaredly comprises insects in its field of application: according to the reasoning that the Advocate General carried on and that was probably considered in the judgment at stake, this would automatically mean that insects had to be included also in the scope of the old novel food regulation.

Going back to the EU Judge's analysis, it fails to consider a further detail in the wording of Article 1 (2), letter c) of the Regulation, which could help – without being determinant – to solve the hermeneutical issue. It refers to "*foods and food ingredients with a new or intentionally modified primary molecular structure*". The fact that an intentionally modified molecular structure is mentioned might suggest that the provision is referring to the result of a human manipulation or – as for the "new molecular structure" – to the result of a human activity on the substance. The novelty would thus refer to a molecular structure that was newly created and did not exist as such in nature: it might me a structure created ex novo or an existing structure deliberately adapted. In both cases, the substance will be a "novel food". If we support such reading - that the Court had not even considered - we could deem the EU Judge reasoning as having provided an extensive interpretation of an exceptional norm. This is not forbidden, but as the Court stated in past cases «*any extensive interpretation must be undertaken only with caution*»[8] and «*any derogation from or exception to a general rule must be interpreted strictly*»[9]. In the judgment at stake, the EU Court, though providing a reading that partially overthrows the regulation wording, might justify such an extensive interpretation under the attempt to fulfil the purpose of the act.

The main element of the EU Judge decision grounds on the fact that the exclusion of substances of mineral origin from the application of the novel food regulation would turn into a lack of protection for human health. Even though the wording does not expressly comprise minerals in any of the categories listed in the Regulation, considering them as not included in its scope would mean letting substances that had never been consumed as food entering the market without prior risk assessment (points 32 and 33). According to the Court, such a solution would bring to an absurd result, contrary to the ratio of the Novel Food regulation which "*aims to establish common standards […] in particular […] by introducing a single safety assessment of those foods and food ingredients through a Community procedure before they are placed on the EU market*".

As we told above, the explanation of such a solution is cogent if we consider the fundamental need to protect consumers' health, which appears to be one of the exigencies emerging from the novel food regulation.

It might be thornier trying to relate this solution also to the intention of the Legislator. As we said earlier, if it had meant to include in the regulation any substance that had not been significantly consumed as food prior to May 1997, the EC Legislator would not have provided a list of specific categories to qualify a food as novel. This should imply that the Legislator was thinking to some categories of food that, though not having been part of the EC consumers' diet prior to that date did not require an official risk assessment. In this perspective, the creative interpretation of the Court has probably gone too far.

Unfortunately, the unsoundness of such reasoning affects also the new Novel Food Regulation. We mentioned the new act some lines above, when referring to substances of mineral origin. Let's instead consider the wording of the new provision on food with a new molecular structure (the adjective primary has disappeared): "*food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997*". This is something

(7) Actually, we should also consider what the Court concluded in the Man Koso case. See note 4.
(8) Judgment of the Court (Second Chamber) of 24 November 1983, - *Hartog Cohen v Commission of the European Communities*, case C-342/82.
(9) Judgment of the General Court (Fourth Chamber, Extended Composition) of 25 January 2017, *Rusal Armenal ZAO v Council of the European Union*, case T-512/09.

rivista di diritto alimentare
www.rivistadirittoalimentare.it
Anno XI, numero 3 · Luglio-Settembre 2017

astonishing, since, while defining when a molecular structure is new, it clearly duplicates, without any reason, the first general condition that shall apply. But if a molecular structure is new when it had not been used as food or in food before 15 May 1997, why specifying also a different class for substances of mineral origin? Could not they be included in the group of substances with a molecular structure that were not used as food or in food prior to the mentioned date?

If not, this means that the category of "food with a new molecular structure" shall not encompass minerals (and also the old novel food regulation shall be interpreted in this perspective, since there are no significant changes, except for the clarification on the meaning of "new").

If otherwise the category of food with a new molecular structure shall include also minerals, the specific provision of the most recent Regulation proves to be useless. This becomes even truer when considering that the provision on food with a new molecular structure applies irrespective of the molecular level (primary or secondary structure). Any substance, either consisting of, isolated from or containing a material of mineral origin, being – as first condition applicable to any food – a food that was not used within the European Union before May 1997, would automatically be a food with a structure that had not been used before May 1997 in food.

The only means to find a sense to the provision is thus recognising that substances of mineral origin do not fall into the category of "food with a new molecular structure", either primary or not.

The wording of the new Regulation actually reflects one of the reasons beneath its adoption: it answers the scientific and technological developments occurred since 1997 (whereas No 8) which emphasises the shortcomings of the old provisions, and clarifies some of the categories listed in the previous text[10]. So, besides the mentioned changes on food of animal origin and food with a new molecular structure classes, and the inclusion of the category of substances of mineral origin, the new Regulation expressly applies to food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae; to food consisting of engineered nanomaterials and to food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements [Article 3, paragraph 2, let. a), points vi, viii, x].

The new provisions try therefore to solve some of the interpretative issues that had arisen in the past years, like the one solved by the Court in the judgment we are commenting on.

6.- Concluding remarks

After having analysed the EU Court's reasoning we could be still torn between supporting and opposing its solution[11]. The need to protect human health as ultimate goal of the Novel Food Regulation is the sole motive to approve the Judge's findings but yet there are some weaknesses on the reasoning: the nullification of the coexistence of the two conditions that characterise the definition of "novel food"; a lack on considering the whole wording of the phrase referred to food or food ingredients with a new or intentionally modified primary structure; the questionable hermeneutical process of extending an exceptional provision; the peculiar reading offered to the legislative intent. While we could share the results, the method might be debatable[12]. What cannot be easily coped with is the forced reading, wil-

([10]) The Regulation further aims to simplify the procedure for placing on the market food with a history of safe use in third countries: it requires the operator to submit a simple notification rather than starting the general authorisation procedure. In the event of reasoned safety objections by Members States or by EFSA, however, the Commission shall not authorise the placing of the market of the "new" product, but the operator may introduce a different procedure, similar to the ordinary one.

([11]) A special thanks to prof. Vito Rubino for his priceless advice on the Court's role and functions.

([12]) The international literature on the theme recognises that criticism over Court's case law is focused «on the lack of sustained reasoning» rather than on the outcomes reached by the Court. Muir E., Dawson M., De Witte B., *Introduction: the European Court of Justice as a political actor*, in Dawson M., De Witte B., Muir E. (eds.), *Judicial Activism at the European Court of Justice*, Cheltenham, 2013, pp. 3-4.

rivista di diritto alimentare
www.rivistadirittoalimentare.it
Anno XI, numero 3 · Luglio-Settembre 2017

ling to submit to authorisation any food, for the sole reason that it had not been used for nutrition prior to 1997 and irrespective of the necessary coexistence of the two conditions required by the Regulation. From the wording of the judgment, it emerges that the Court pursues the intent of submitting clinoptilolite to the authorisation procedure, in order to ensure food safety (points 31-33). It then builds its interpretation with this purpose in mind. The impression one could have is that the Judge has constructed its argumentation starting from the result it wanted to obtain, instead of reaching a solution through a step-by-step logical reasoning. The Court had the unpleasant task of making up for the gaps and the unclearness left by the Legislator but we might wonder to which extent this could be done: could the EU Judge pursue the purpose of an act, while rendering ineffective - though for a very peculiar situation - one of its fundamental provisions? This doubt recalls scholars' debate on the Court as policy maker and on its activism[13], that is to say on its role as law maker[14]: the perception that the Court had construed (and not simply interpreted) EC law according to the objective that the Judges were pursuing[15] perfectly matches the idea of a "teleological judicature" on which several scholars debated[16]. This is not a matter of integration between national legal orders and the EU one, as it was in past years, when the dispute on judicial activism was at its utmost level[17]. It is just a question on the extension of the Court's powers and on legal certainty. In the case at issue, the EU Judge pushes its interpretation till the area of legislative creation: it does not simply offer a reading of the normative text. It removes part of a constitutive provision (i.e. the need for the second condition) and adds a broader significance to the remaining words, despite the structure of the Regulation gives evidence that the Legislator intentionally formed a list of limited categories for novel foods and set two conditions for defining a food ingredient as "novel". In EU national orders, this could be perceived as a trespassing of the tripartite separation of powers, the Court having actively created a "new" provision, with the exemption of clinoptilolite from the coexistence of two conditions: it is a novel food just because it had not been used significantly as food prior to 15 May 1997. However, the role of the EU Court of Justice and the configuration of the EU legal order[18] are so peculiar that the Montesquieu doctrine might not apply[19]. As Advocate General Trstenjak stated in her opinion in case C-101/08[20], «*The institutional balance within*

(13) This is actually the same question that Ramussen H., *Between Self-Restraint and Activism: A judicial Policy for the European Court*, in *European Law Review*, 1988, pp. 28-38, tries to solve when wondering: "*How liberally may the Community judge, following his perception of the (correct) policy-orientation, which ought to prevail in judicial decision, give preference to teleology over text*", p. 33. Conway G., *The Limits of Legal Reasoning and the European Court of Justice*, Cambridge, 2012, defines the term "activism" as "*having a sometimes pejorative connotation of excessively creative interpretation or interpretation that approximates legislation*", p. 17 and p. 61. On the topic, please refer also to Sankari S., *European Court of Justice Legal Reasoning in Context*, Groningen, 2013, pp. 47 ff.

(14) The role of judges in "creating" or "shaping" law has been discussed for years. In 1968, M. Lupoi published a paper headed *Il giudice legislatore: una recente esperienza inglese*, in *Il Foro it*., 1968, vol. 91, 7-8, V, col. 546-590, focusing on the judgment of the British House of Lords in *Conway v. Rimmer.* The Author emphasised the lawmaking role (col. 550) that the Judge had to play, due to the Parliaments's inertia (col. 549), while deciding to depart from the judicial precedent. For an historical analysis from several points of view, please refer to Vv. Aa., *Giudici e giuristi. Il problema del diritto giurisprudenziale fra Otto e Novecento*, in *Quaderni fiorentini*, 2011, 40, I and II, pp. 1 ff.

(15) Albors Llorens A., *The European Court of Justice, More than a Teleological Court*, in *The Cambridge Yearbook of European Legal Studies*, 1999, 2, p. 373.

(16) Albors Llorens A., *cit.*, p. 373, makes a review of the different positions on this topic. While criticizing the selectiveness of all such studies, the Author tries to offer a comprehensive contextualised view.

(17) Lenaerts K. – Gutiérrez-Fons J.A., *To Say What the Law of the EU Is: Methods of Interpretation and the European Court of Justice*, in *Columbia Journal of European Law*, 20, 2014, 2, pp. 34 ff.

(18) Since the Van Gend en Loos case 26-62, the Court has been stressing the peculiarity of the EC legal order as something new and different from the systems of the Member States.

(19) Conway G., *The Limits of Legal Reasoning and the European Court of Justice*, Cambridge, 2012, p. 192, and *Recovering a Separation of Powers in the European Union*, in *ELJ*, 17, 3, pp. 304-322.

(20) Opinion of Advocate General Trstenjak delivered on 30 June 2009, *Audiolux SA e.a v Groupe Bruxelles Lambert SA (GBL) and Others and Bertelsmann AG and Others*, case C-101/08.

rivista di diritto alimentare
www.rivistadirittoalimentare.it
Anno XI, numero 3 · Luglio-Settembre 2017

the Community is not based on the principle of the separation of powers in the constitutional-law sense, but on a principle of the separation of functions, whereby the Community's functions are intended to be exercised by the organs which are best placed to perform them under the Treaties. Unlike the principle of the separation of powers, which seeks partly to ensure that the individual is protected by moderating state power, the principle of the separation of functions is intended to ensure that the Community's aims are effectively achieved» (point 104).

Under such assertion, if we consider the objective of food safety and health protection pursued by the European Union, the Court's findings become much more reasonable.

Yet, it is undeniable that the difficulty to accept the judgment in case C-448/14 still survives, due probably to the fact that any scholar or commentator cannot avoid to be influenced by the national legal order and tradition to which he or she belongs[21], thus seeking for the boundaries that limit the Court's function.

This becomes even more perceptible in the case at issue, where, following the judgment, a food business operator will be required to withdraw the products from the market, though he or she had started the marketing on the basis of the textual reading of the Regulation. To what extent can the EU Judge overshadow the principle of legal certainty?

Article 19 of the Treaty on European Union states that the Court shall ensure that «*in the interpretation and application of the Treaties*» (but we can extend the provision also to secondary legislation) «*law is observed*». So we could infer that the Court's judgment is not questionable as far as it complies with the law. If there had been a clear provision excluding substances of mineral origin from the novel food regulation or if the definition of "new primary molecular structure" were sufficiently determined as to clearly exclude clinoptilolite from the scope of the act, the Court's solution would have been objectionable. Where there is ground for interpretation, however, the food business operator could not claim for legitimate expectations or for the wider legal certainty recognition, since a certainty, actually, does not exist: the wording of the Regulation was not unambiguous; consequently a preventative approach pre-emptively asking for the national authority's opinion, would have been far more prudent than the direct marketing within the European Union. In balancing health protection and free movement of goods, the Court of Justice can legitimately ensure a wider shelter to the former, above all when – as in the case at issue – the effect on the food business operator's part is "just" a temporary stop on the sales, until the completion of the authorisation procedure.

The creativity of Courts' interpretation is something that is immanent in the judiciary activity: when judges rule over a case, while applying law (but this is true also with reference to judicial precedent), they do not merely mechanically implement a provision. They perform a legal reasoning that inescapably is somehow creative and discretional. The problem is to determine the limits of such creativity.

Scholars recognise that the pluralism of values has been shaping the regulatory power of law, weakening its binding capacity and turning the executive moment merely into a matter of Judges' choice[22]. The vagueness of provisions, in other words, legitimises those options implemented by the Court on the basis of the spirit of law.

Indeed, the debate over the changing role of Courts, shifting from simple execution to creation of law has been going on for years, in both common law and civil law systems.

This transformation has been perceived as the necessary consequence of modern and postmodern times, where new issues and new needs (eco-

([21]) As Tridimas T. states in *The Court of Justice and Judicial Activism, in European Law Review*, 1996, p. 200, «*Whether a decision is active or not depends on one's standpoint*». On such point, a remarkable analysis is carried out by Arnull A., *Judicial activism and the European Court of Justice: how should academics respond?*, in Dawson M., De Witte B., Muir E. eds., *Judicial Actvism at the European Court of Justice*, Cheltenham, 2013, pp. 211-232. As Tridimas T. states in *The Court of Justice and Judicial Activism*, in *European Law Review*, 1996, p. 200, «*Whether a decision is active or not depends on one's standpoint*».

([22]) Caretti P., *La giustizia arbitrale: una riflessione sulla legittimazione della giurisdizione*, in *Scritti in onore di Gaetano Silvestri*, Torino, 2016, v. I, p. 448.

nomical, political, constitutional, social)[23] arise and compel the Judge to play the role of problem-solver and policy-maker[24]. As told above, Courts do create law[25] but this does not imply that they become Legislator[26]: they simply enact - and this is more perceptible when referring to the Court of Justice of the European Union – their role of reading and implementing the law through the lens of changing times.[27] Every so often, however, they bear the burden of remedying to the «*law decadence*» and the «*fragmentation of the precept source system*», thus turning from «*judges of the single case*», to «*regulatory courts*»[28]. This happens above all in national legal orders: much has been said, in this regard, about the creative role of the Judge.

In Italy, for instance, the debate on this issue, that is still animated[29], involves almost any branch of the law (civil[30], administrative[31] and, to some extent, criminal law[32]), at different levels (from first instance Court to the Supreme Court) as well as different subjects (scholars, practitioners and judges) and becomes even more pressing when considering the «*de-statualization of the sources of law*»[33].

The main finding is however comparable: the Court's active intervention is a necessary step in contemporary legal scenario, above all in the European Union context. The novelty of some issues, the necessary generality and abstraction of law, the impossibility of acts to provide an articulated specific solution for any possible factual circum-

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([23]) Cappelletti M., *Giudici legislatori?*, Milano, 1984, p. 63.

([24]) Taruffo M., *Sui confini. Scritti sulla giustizia civile*, Bologna, 2002, pp. 153-154. On the interpreter's role and on the «*innovative power of time*», Cappelletti M., *op.cit*., p. 12. On the political features of the judiciary activity, Rodotà S., *Magistratura e politica in Italia*, in Bruti Liberati E. – Ceretti A. – Giasanti A. (eds.), *Governo dei giudici. La magistratura tra diritto e politica*, Milano, 1996, p. 23.

([25]) Lord Reid, *The Judge as Law Maker*, in *J. Soc'y Pub. Tchrs. L.*, 22, 1972-1973, pp. 22 ss.

([26]) Cappelletti M., *cit.*, p. 64.

([27]) The statement that "Judges create law" committed Italian scholars' debate for years, as recalled by Carriò G. R., «*I giudici creano diritto» (esame di una polemica giuridica)*, in Scarpelli U. (ed.), *Diritto e analisi del linguaggio*, Milano, 1976, pp. 397-406. Contrary to this interpretation, Grossi P., *La invenzione del diritto: a proposito della funzione dei giudici*, inaugural speech for the opening of the 2017 training courses at Scuola Superiore della Magistratura, par. 8, states that the Judge does not create law, since even the Legislator does not have this ability: law is something that pre-exists and has just to be found by the interpreter. The text of the speech is available at the following URL http://www.cortecostituzionale.it/documenti/interventi_presidente/Grossi_Scandicci.pdf [05.09.2017].

([28]) Albisinni F., *Prodotti alimentari o agroalimentari? Il TAR del Lazio, giudice del mercato e law maker, smentisce il MIPAAF e l'AGCM*, in this *Journal*, www.rivistadirittoalimentare.it, 3-2013, p. 39. Similarly, Pardolesi R.-Pino G., *Post-diritto e giudice legislatore. Sulla creatività della giurisprudenza*, in *Foro it*., 2017, 142, 3, p. 114.

([29]) Grossi P., *La invenzione del diritto: a proposito della funzione dei giudici, cit.*, in particular para. 6-8. Vv.Aa., *Il Giudice e la legge*, in *Questione giustizia*, 2016, 4, pp. 3 ss.

([30]) A comprehensive study on this topic started in the middle of Sixties, when G.Gorla launched an investigation on the importance of case law (or judicial activity), with a comparative research on «common law». The Author explained the reasons for such an analysis in G. Gorla, *Lo studio interno e comparativo della giurisprudenza e i suoi presupposti: le raccolte e le tecniche per la interpretazione delle sentenze*, in *Il Foro it.*, 1964, vol. 87, 7, parte V, col. 73-87 (see, in particolar, col. 73). For a contemporary overview on the role of the Judge in creating law, above all under a civil law point of view, please refer to Lipari N., *Il diritto civile tra legge e giudizio*, Milano, 2017. Please refer also to Pardolesi R.- Granieri M., *Dottrina delle corti e disimpegno dei giuristi*, in *Foro it.*, 2013, V, col. 187.

([31]) Pajno A., *Inaugurazione dell'anno giudiziario 2017*, speech held on January 31, 2017, available at-https://www.giustizia-amministrativa.it/cdsintra/cdsintra/Notiziasingola/index.html?p=NSIGA_4269449 [05.09.2017], who refers to the mobile borders among Legislator, Administration and Judge, even in civil law systems, where sources are depreciated, Laws become administrative acts and lose their characters of generality and abstraction and Judges create rules. See also Albisinni F., *Prodotti alimentari o agroalimentari? Il TAR del Lazio, giudice del mercato e law maker, smentisce il MIPAAF e l'AGCM, cit*., and Id., *Interpretazione conforme al diritto UE e diritto agrario: verso un diritto comune dell'agricoltura*, in Bernardi A. (ed), *L'interpretazione conforme al diritto dell'Unione europea. Profili e limiti di un vincolo problematico*, Napoli, 2015, p. 253, with reference to both the Italian civil and administrative Supreme Courts.

([32]) As for criminal law, the impact of the fundamental principle of "*riserva di legge*" (principle that could be summarized in the brocard «*nullum crimen nulla poena sine lege*» and which would have abstractly inhibited the "judicial creation of law") appears to have weakened, or at least changed. Borsari R., Diritto *penale*, *creatività e co-disciolinarità*. *Banchi di prova dell'esperienza giudiziale*, Padova, 2013, pp. 18 ss. See also Manes V., *Il Giudice nel labirinto. Profili delle intersezioni tra diritto penale e fonti sovranazionali*, Roma, 2012, pp. 22 ss.; Fiandaca G., *Crisi della riserva di legge e disagio della democrazia rappresentativa nell'età del protagonismo giurisdizionale*, in *Criminalia*, 2011, pp. 79-98; Donini M., *Europeismo giudiziario e scienza penale. Dalla dogmatica classica alla giurisprudenza-fonte*, Milano, 2011, pp. 53-54.

([33]) The expression is used by Lipari N., *Il diritto civile tra legge e giudizio*, Milano, 2017, p. 27, who puts emphasis on the EU Court's role as law-maker, p. 29, and on the judicial aspects that characterize EU law, p. 30.

rivista di diritto alimentare
www.rivistadirittoalimentare.it
Anno XI, numero 3 · Luglio-Settembre 2017

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.