SUMMARY

The title of the monograph "The placing of novel foods on the EU market in the light of new EU regulations" requires clarification. The notion of novel food includes food that was not used for human consumption to a significant degree within the European Union before 15 May 1997, and falls into at least one of the legally distinct categories. Examples of novel foods are: chia seeds, *Echium plantagineum* oil, phytosterols, Dextran preparations, Noni fruit juice (*Morinda citrifolia*) or exotic fruits. "The placing of food on the market" is understood very broadly and means not only selling, distributing or otherwise disposing of food, but also possessing or offering food for purchase to be subsequently used for the above purposes.

The regulatory research area comprises primarily EU Regulation No. 2015/2283 and its implementing regulations. A particular difficulty arises from the fact that Regulation No. 2015/2283 has only been in force since 1 January 2018, but is intended as a continuation of the existing solutions which prevailed for over 20 years, without fundamentally changing their scope. The considerations must take into account both the current regulations on novel foods and, as far as is appropriate, those that have already expired. The aim of the new regulations is to update the basic terms, shorten and reduce the costs of authorisation proceedings, introduce centralised risk assessment and food safety, simplify the procedures for placing traditional food from third countries on the EU market and protect the data of scientific innovators.

There are various reasons justifying the choice of the subject matter defined in the title of the monograph, in particular cognitive, socio-economic, agri-environmental and theoretical ones. As far as cognitive reasons are concerned, it should be noted that this topic has not yet been recognised in detail. Novel food is often confused with functional food, fortified food or genetically modified food. Socio-economic reasons play a very important role too. Novel food may contribute to food security understood as people's access to adequate amounts of food. On the other hand, novel foods, without experience of safe consumption, may pose a threat to the health and life of consumers. Agri-environmental reasons are also important since novel foods may pose a threat to the environment and, consequently, to human health and life. As regards theoretical considerations, the monograph addresses the basic conceptual categories of food law.

The determination of the research objective requires some initial assumptions. The first is that the considerations should take into account innovation occurring in agriculture. The second expresses the need to take into account the impact that regulations on novel foods have on the functioning of the internal market. The third assumption consists in tak-

ing into account the economic, social and environmental effects of placing novel foods on the market. The fourth expresses the need to include in the research the agricultural and food aspect of regulations.

The assumptions consequently adopted allow us to specify the aim of the research, which is an attempt to answer the question of whether and to what extent the legal regulations concerning the marketing of novel foods in the EU, in particular Regulation No. 2015/2283 and its implementing regulations, protect human health and life, whilst ensuring the free movement of such foods in the EU and protecting the economic interests of both consumers and food business operators.

The structure of the work follows the line of argument set by the goal set and the main strands of the problem. The monograph is divided into seven chapters, of which five are substantive chapters serving the research objective. In order to achieve the aim of the work, dogmatic, empirical and historical methods were used. This book is based on the legal situation in force on 1 May 2019.

The considerations which have been carried out provide the basis for the final answer to the questions raised in the introduction to the monograph. When evaluating the legal regulations concerning novel foods and formulating the final thesis of the work, the assumptions first adopted are taken into account.

The first question to be answered is whether and to what extent regulations on the marketing of novel foods in the EU protect the health and life of consumers.

The conclusion that may be drawn from the considerations is that the regulation of novel foods protects human health and life sufficiently. The safety of such foods is not only influenced by the relevant legal instruments, but also by their application. The thesis that the existing regulation is adequate is further confirmed by the fact that so far there has been no risk recorded in the EU related to the consumption of novel foods placed on the EU market in accordance with the adopted solutions, i.e. both Regulation No. 258/97 and Regulation No. 2015/2283. The effectiveness of food law in the area of the protection of human health and life is best demonstrated by the lack of negative experiences related to food consumption. What is more, Regulation No. 2015/2283, compared to Regulation No. 258/97, reduces the administrative and financial burden for applicants. Further, by updating the definition of novel foods it removes the differences in the application of the provisions applied in the Member States and reduces legal uncertainty by facilitating the appropriate qualification of the product. In this way, it addresses the root causes underlying the illegal placing of novel foods on the European Union market and the failure of food business operators to regulate such foods.

This is the point where an answer to the question of whether the regulations on novel foods ensure the free movement of novel foods in the EU is needed.

The limited legislative activity of Member States in the field of novel foods excludes the possibility of setting additional requirements of an arbitrary nature that could affect the free movement of goods within the EU. At the same time, it should be noted that the objective of food law, the free movement of food, is conditional and concerns safe food only. The priority in food law is always the protection of people's health and life, the guarantee of which determines in a way the possibility of ensuring the free movement of safe food in the EU. The unification and harmonisation of legislation may be an effective instrument for ensuring food safety and its free movement in the EU. Since it is impossible to speak

of absolute safety, Member States should have the opportunity to intervene effectively in the event of risks emerging.

A violation of the free movement of goods and a negative impact on the functioning of the internal market may result not so much from law-making as from the application of the law. Despite uniform EU regulations and the establishment of a common definition of novel foods in the EU, discrepancies may arise in the understanding of the wording and notions used in the legislation. Differences in the interpretation of EU provisions may therefore provide a basis for self-regulation by Member States, which may in turn have a negative impact on the free movement of food within the EU.

It is therefore legitimate to conclude that the regulations on the placing of novel foods on the EU market do not have an adverse effect on the functioning of the internal market, but their non-uniform application may impair the free movement of safe novel foods in the EU.

The next question to be answered is whether arrangements involving the placing of novel foods on the EU market provide sufficient protection of the economic interests of consumers.

It should be pointed out that the basic instruments for the protection of consumers' economic interests are labelling requirements. Compared to the previous Regulation No. 258/97, Regulation No. 2015/2283 does not specify the scope of the data to be provided to purchasers, but prescribes that the authorisation should specify on a case by case basis what information should be provided to the consumer. This solution must be considered appropriate. This definition of the information to be provided each time to the consumer will allow the most effective and efficient solutions to be adopted. It must therefore be concluded that the regulations on novel foods protect consumers' economic interests sufficiently. In future, however, their effectiveness and efficiency will depend on the coordination of the application of novel food legislation with that of general labelling obligations.

Finally, the question of whether novel food regulations protect the interests of food business operators must be answered.

The application of Regulation No. 2015/2283 may constitute undue barriers to trade for food business operators. SMEs may encounter particular difficulties since very high costs and lengthy proceedings limit the ability of smaller operators to innovate. Despite the planned reduction in the length of proceedings, the new regulations are unclear and imprecise in determining the length of proceedings, leaving a lot of leeway to the authorities conducting them. It seems that costs will not be significantly reduced either. The applicant will still be responsible for proper product qualification and will have to carry out the first tests and establish and prove the safety of novel food.

The legislator does not foresee any support schemes for operators intending to place novel foods on the European Union market. Although policies and programmes have been adopted to increase the innovation of the economy, they do not generally address the issue of novel food. The only determinant of using new food production methods and importing unknown foods is therefore the economic benefits that pioneers are likely to gain.

In order to encourage food business operators to place novel foods on the EU market, which is a costly and time-consuming investment, it is necessary to ensure that innovations implemented at a significant economic cost are protected. Therefore, the period of protection for new scientific data during which the applicant is the only person allowed to place

a novel food on the EU market should be assessed positively. It aims to stimulate research, development and innovation in agriculture and the agri-food industry, in particular by protecting the costly investments made by applicants in gathering information and data to support any application for novel foods. In this way the impetus and encouragement of the food sector will be ensured and provided. Unfortunately, the five-year period may turn out to be too short and may only cover part of the expenditure incurred.

The introduction of new, simplified solutions for food traditionally consumed which already has a history of safe consumption in non-EU countries, should also be welcomed. However, such regulation may constitute a barrier that is difficult to overcome for most food business operators. The problem is how to document product safety for over twenty-five years of continuous use and what evidence to rely on. It may in fact be that such evidence will only begin to be collected and the demonstration of a history of safe food use will only be possible in a few years or longer.

The considerations carried out allow the final conclusion of the work presented in the monograph: the legal instruments for placing novel foods on the EU market ensure their safety, and protect sufficiently the economic interests of the consumer, although they may constitute an excessive barrier for business operators. They may hamper innovation and, above all, may result in novel foods being placed on the EU market without protective regulations, in particular without pre-market safety assessment and authorisation. Meanwhile, threats to the functioning of the EU internal market, and especially to the free movement of safe novel foods in the European Union, may be seen in the non-uniform application of the law.

The formulation of *de lege ferenda* demands is difficult as Regulation No. 2015/2283 has only been in force for a little over a year, i.e. since 1 January 2018. And yet, three *de lege ferenda* proposals may be formulated. They are, however, of a general nature due to the short duration of the provisions under consideration.

The first is to ensure clarity and transparency in the regulations on novel foods. Although the vague formulation of terms in legislative acts is a deliberate and desirable action of the legislator, especially in such a specialised and rapidly changing field, the existing doubts, which are not explained by the new regulations, have significantly limited the introduction of innovations onto the EU market. Difficulties related to understanding certain concepts, and consequently – differences in the interpretation of the law, may have a negative impact on the effective assessment of food safety and the length of the proceedings. This may constitute an obstacle to the introduction of novel foods on the EU market and, as a result, limit the flow of food into the EU.

Another proposal concerns greater support for the food sector in terms of innovation. It addresses three issues where there is a need to: reduce the impact of policies on the proceedings for placing novel foods on the market, increase support for SMEs, in particular by protecting their competitive position, and review the procedure for placing traditional foods from third countries on the EU market.

As regards the need to reduce the impact of policies on the conduct of proceedings for the placing of novel foods on the EU market, it should be pointed out that the misuse by Member States of legal measures with the intention of delaying or restricting the placing of safe novel foods on the EU market may be socially, economically and socially harmful.

Therefore, EU and Member State bodies would be expected to take on the role of guardians preventing novel foods from being placed on the EU market only where they are likely to endanger human health and life. It should be pointed out that in this regard what is needed is verification of the application of EU law by individual Member States rather than a change in the existing legislation.

As regards the proposal to increase support for SMEs, it should be stressed that under the current legal framework, launching innovations on the food market, which represents costly and time-consuming investments, may be considered unattractive and economically unjustified for smaller operators. A factor that discourages innovative activity is also the opportunity created for other market participants to use the specific achievements of other operators. Although the new legal solutions providing for a period of data protection should be approved, they may not bring the desired result due to a too short, only five-year, protection period. An extension or a controlled licensing system might be advisable. The solution of both voluntary and compulsory licensing will allow the sharing of the costs of innovation among the other food business operators concerned. However, care should be taken to ensure that the support systems introduced would not, in effect, affect the quality of food, or, result in the monopolisation of the market by large companies and global, multinational corporations that make SMEs dependent on them.

As regards the verification of the procedure laid down for traditional foods from third countries, it should be noted that the mere simplification of the procedure for such foods deserves a positive assessment. However, the instruments indicated in Regulation No. 2015/2283 may prove to be insufficient. In particular, the period of twenty-five years of safe consumption, which must be demonstrated in the application, should be reviewed. One reason for this may be the difficulty of collecting data over such a long period of time, as it might considerably restrict the consumption of novel foods despite their safe consumption in third countries for years. However, a reduction in the duration of such generational studies should nevertheless be without prejudice to the fundamental objective of food law to ensure food safety.

The last proposal requires an evaluation of the effectiveness of Regulation No. 2015/2283. Not only the legal instruments adopted but also the effectiveness of their application should be examined. A review of these solutions is necessary in order to meet present day requirements , but also, by taking appropriate and proportionate measures, to allow the placing of safe novel foods on the EU market.

The implementation of the proposals presented above may help to remove the major shortcomings of the Regulation in question. Clarification of the doubts presented may limit the negative impact of the application of the adopted solutions on the free movement of safe food in the EU. On the other hand, support schemes may contribute to the elimination or reduction of the existing barriers affecting food business operators, in particular SMEs, and consequently to the opening of the EU market to safe food innovations. The last proposal would seem obvious as it provides for the necessity of reviewing the effectiveness of new legal regulations which, although in force for only a dozen or so months, update the provisions binding, almost unchanged, for over twenty years. The proposed changes should primarily serve to protect the health and life of consumers, which is the most important and also the unconditional objective of food law.