**Increasing legal certainty without trust: why Regulation 2019/515 cannot achieve the unachievable**

*More than 40 years following Cassis de Dijon, the mutual recognition in the field of goods is still a failure. The promise of this principle for ensuring both market access and regulatory diversity has not been kept. Therefore today businesses rarely rely on mutual recognition to sell their products in another Member State. In an attempt further to stimulate this procedure, the EU legislator tried to simplify the procedures to be followed by businesses and public administrations through Regulation 2019/515. This Article argues that, although the Regulation creates more legal certainty, it fundamentally fails to address the underlying problem of lack of trust that has stalled mutual recognition in the past.*

1. **INTRODUCTION**

Free movement of goods is one of the four fundamental freedoms in the EU and is vital for European competitiveness. It is the most developed fundamental freedom within the Single Market and is ensured through the prohibition of restrictions on intra-EU trade, the harmonisation of legislation and the principle of mutual recognition[[1]](#footnote-1).

The EU institutions may justifiably claim a real success to enhance trade in goods. Today, trade in goods generates around 25% of EU GDP and represents 75% of intra-EU trade[[2]](#footnote-2). However, behind these headline figures, the record is different regarding non-harmonised products and aspects of products falling outside the scope of harmonised legislation. Despite 80% of regulatory barriers in the Single Market for goods having been eliminated or in some way other way addressed, important barriers still remain[[3]](#footnote-3).

In the area of harmonised goods, EU product legislation under the “New Approach”[[4]](#footnote-4) is limited to the adoption of the essential requirements with which products put on the market must conform. To demonstrate compliance with these requirements, manufacturers may voluntarily use European standards created by the European Standards Organisations. When formally recognised by the Commission, these standards become “harmonised standards”[[5]](#footnote-5). Harmonised standards are a powerful tool in support of European policies for product market integration. When economic operators make use of these harmonised standards, they benefit from a presumption of conformity, allowing them to sell their products easily in the Single market[[6]](#footnote-6).

In the absence of harmonisation, Member States remain “at liberty” to adopt national technical rules. However, they have to recognize and give effect to national technical rules or standards of other Member State. Ever since the decision of the European Court of Justice (ECJ) in *Cassis de Dijon* embedding the principle of mutual recognition into Articles 34[[7]](#footnote-7) and 36[[8]](#footnote-8) of the Treaty on the Functioning of the European Union (TFEU), goods lawfully produced in one Member State should be granted unrestricted access to any other Member State’s market, even when those goods were manufactured in accordance with different technical rules[[9]](#footnote-9). However, a Member State may still derogate from this principle by refusing market access to products lawfully produced and marketed in another Member State, on the basis of Article 36 or by mandatory requirements (such as the protection of the environment[[10]](#footnote-10) or the defence of the consumer[[11]](#footnote-11)), subject to the test of proportionality[[12]](#footnote-12).

In the best of worlds, the strategy to make mutual recognition a tool to deal with the non-tariff barriers to increase intra-EU trade seems suitable since it respects national diversity and avoids harmonisation and centralization. Partially and non-harmonised products would have unrestricted access to other Member States except when duly justified. The outcome would include more choices for consumers at lower prices and more opportunities for companies, especially micro enterprises and SMEs who are the primary players in the field[[13]](#footnote-13).

Unfortunately, the principle gave way to reality as the application of the principle of mutual recognition on the basis of the provisions of the Treaty and of the decision in *Cassis de Dijon* proved challenging in practice without any secondary legislation to make it work. The secondary legislation can be divided in *ex-ante* and *ex-post* stages. The *ex-ante* stage is Directive 2015/1535[[14]](#footnote-14), which obliges Member States to give a prior notice to the Commission when they draft a new technical rule[[15]](#footnote-15). The *ex-post* stage – Regulation 2019/515 (“the Regulation”) and that repealed Regulation 764/2008 – intends to make sure that all Member States observe the principle of mutual recognition in individual cases in relation to goods which are subject to Article 34 TFEU and which are lawfully marketed in another Member State.

Notwithstanding the liberal interpretation by the ECJ of the notion of the “prohibition of measures having an effect equivalent to quantitative restrictions”[[16]](#footnote-16) and the secondary legislation that has been introduced to put flesh and substance on the concept of mutual recognition, how far do barriers to trade in the non harmonized area continue to exist? In examining that, this paper highlights the relevance of mutual recognition in the Single market (section II). Then, it offers a brief abstract of the lack of trust between Member States (section III) and the now repealed Regulation 764/2008’s regime (section IV), followed by an overview of the new Regulation (section V). It then examines the Regulation’s innovations as regards the scope of mutual recognition (section V, 1, a)) and the application of mutual recognition (section V, 1, b)) through (i) the mutual recognition declaration, (ii) the new assessment of goods and (iii) temporary suspension of market access and the new problem-solving procedure. Finally, the main points are summarized in a conclusion (section VI).

1. **RELEVANCE OF MUTUAL RECOGNITION IN THE SINGLE MARKET**

In general terms, economic operators recognise the importance of the principle of mutual recognition but are not satisfied by its implementation across the EU[[17]](#footnote-17). Non-harmonised products represent 18% of the value of intra EU exports[[18]](#footnote-18).

Mutual recognition is a necessary complement to harmonised standards for product market integration. Relying solely on harmonised standards in free movement of goods is not feasible[[19]](#footnote-19). Firstly, these standards do not exist in certain sectors (e.g. food supplements[[20]](#footnote-20)). Secondly, European standards are harmonised through a time-consuming process[[21]](#footnote-21). Mutual recognition can achieve similar results to harmonisation with the advantage of not triggering transaction costs that occur with harmonisation when businesses need to comply with new harmonised standards[[22]](#footnote-22). It is particularly important for SMEs, primary players in the non-harmonised area.

Furthermore, mutual recognition plays a central role in supporting innovation when economic actors want to sell their products outside their Member State[[23]](#footnote-23). For new innovative products, there are no European standards and businesses need to rely on national rules or standards. In 2016, four in ten EU companies have introduced new or significantly improved products[[24]](#footnote-24).

The success of the mutual recognition of non-harmonised goods regime depends upon the level of trust between Member States. Whereas harmonisation at the European level requires centralization and is a costly process, mutual recognition “simply” requires the importing (host) Member State to recognize the national rules of the exporting Member State. Everyone in principle wins: on the one hand, Member States avoid costs of *ex-ante* harmonisation and their autonomy to regulate their own national goods remains ensured. On the other hand, businesses avoid the costs of having to adapt their products to meet the national rules of the importing or host Member State.

1. **MUTUAL LACK OF TRUST**

Products lawfully manufactured or marketed in one Member State should in principle move freely within the Single market except under exceptional circumstances. The practical implementation of the principle showed the opposite[[25]](#footnote-25). Member States tend to apply their national rules or require additional tests and certifications for products entering the market.

The mutual recognition principle is not as simple as it may appear, two aspects of it explain its potential weaknesses.

Firstly, as was highlighted by Maduro, mutual recognition is “not simply a rule allocating regulatory competences among states”[[26]](#footnote-26), it is also a form of governance[[27]](#footnote-27). Mutual recognition entails regulatory competition between Member States. Maduro states that “mutual recognition does not determine the final regulatory outcome but sets in motion a process of regulatory competition that is governed by a particular form of market (composed of both economic and political transactions). It is to this market that mutual recognition entrusts regulatory competition and it is this market that is a mode of governance”[[28]](#footnote-28). Beyond the debate on whether this competition is a race to the bottom, what is important to observe here is that national rules compete with each other regardless of the final outcome.

Secondly, with mutual recognition, host Member States on their own territory do not have control over the rules applied on imported goods from other home Member States. Therefore, as Schmidt notes: “regulation falls exclusively under the responsibility of the home state”[[29]](#footnote-29). The control is in the hands of the home Member State and “implies a horizontal transfer of sovereignty”[[30]](#footnote-30) from the host Member State as to what products can be sold on its market. This point is particularly important because it implies two things. First, the host Member State strongly relies on how seriously home Member States regulate their own market. In other words, a Member State has to trust the others enough because it has no longer the control over the production and marketing of goods that are imported into the host state. Second, it also means that, despite different regulatory cultures, host Member States have to recognize different level of risk regulation by home Member States.

Still, the mutual recognition principle is not a rigid concept. The derogations in Article 36 TFEU and the ECJ’s case law leave some control to host Member States. The reason behind these derogations can be explained by the fact that mutual recognition principle is not to be applied blindly. The Treaty allows national measures to derogate from the mutual recognition principle if these measures serve important interests recognized by the European Union as valuable[[31]](#footnote-31) (i.e. the protection of health). Moreover, since *Cassis de Dijon* made “significant inroads into states’ competence to regulate products traded on their territory”[[32]](#footnote-32), the mandatory requirements were the states’ compensation.

In a context where each Member States’ rules compete with each other and where the home Member States are not in control of imported products’ rules, mutual recognition therefore strongly depends on the level trust among Member States.

1. **THE FAILURE OF REGULATION 764/2008**

Regulation (EC) 764/2008 introduced procedural guarantees to allow on the one hand businesses to rely on mutual recognition and on the other hand to allow Member States to deny mutual recognition in compliance with the proportionality principle[[33]](#footnote-33).

The regulation from 2008 however failed to achieve its aim. Businesses considered that the tools put in place were useful and necessary but it did not help them to enter new markets in practice[[34]](#footnote-34). Studies showed that mutual recognition was highly problematic for specific categories of goods such as precious metals, foodstuffs, food additives and food supplements, construction products, fertilisers, automobile spare parts and spring water[[35]](#footnote-35). The impact assessment accompanying the proposal for the (2019) Regulation highlighted the suboptimal use of mutual recognition, which in the end resulted in additional costs on businesses and prevented them from taking advantage of the benefits that mutual recognition was meant to bring[[36]](#footnote-36). The assessment shed light on several issues leading to this failure, such as the “unclear scope regarding the products covered; the difficulties in demonstrating that the product was lawfully marketed in a given Member State; national administrations favoring their own rules; difficulties with challenging authorities’ decisions; and insufficient communication among all actors, including inside and among national administrations, as well as with the Commission, national contact points and companies”[[37]](#footnote-37).

All these reasons led to the adoption of the Regulation, whose aim is to bring changes with the objective of achieving genuine free movement for partially and non-harmonised products.

1. **REGULATION 2019/515 (“THE REGULATION”)**

The Commission in its “Goods package”[[38]](#footnote-38) intended to boost the principle of mutual recognition and simplify the procedures to be followed by businesses and public administrations[[39]](#footnote-39) with the aim of the package being to upgrade the Single Market, thus allowing “more opportunities for people and businesses”[[40]](#footnote-40). Four specific policies objectives were taken into account to that effect: increasing awareness of mutual recognition, increasing legal certainty for businesses and national authorities on when the principle applies and how it is applied and enhancing communication, cooperation and trust among national authorities[[41]](#footnote-41).

Will these ambitious policy objectives be achieved in a context characterized by lack of trust? In the light of the failure of Regulation 764/2008, will the innovations made in the Regulation be likely to improve legal certainty as regards mutual recognition?

1. **The Regulation’s innovations**
2. ***Increasing legal certainty as regards the scope of mutual recognition***

Clarifying the scope of mutual recognition was widely and strongly supported by all stakeholders[[42]](#footnote-42) and as necessary for its workability. Therefore, the Regulation clarifies *the kinds* of products that fall within its scope and the areas where measures restricting or denying market access are allowed even under the mutual recognition principle. Yet, crucially there is no list of *actual* products falling under the scope of the Regulation. Whilst the Regulation’s scope is undoubtedly clearer than Regulation 764/2008[[43]](#footnote-43), it will remain difficult for businesses and national authorities to know in practice which *specific* products fall within the Regulation without any other guidance, especially for the non-harmonised aspects of harmonised goods.

The Regulation now expressly mentions that it covers not only non-harmonised products but also aspects of products that are not harmonised at EU level[[44]](#footnote-44). Moreover, the Regulation applies to administrative decisions that have been taken or are to be taken by a competent authority of a Member State of destination in relation to any such goods that are lawfully marketed in another Member State. In order to solve the confusion made with regards to prior authorization procedures[[45]](#footnote-45), Article 2 paragraph 4 clearly states that these procedures do not constitute a national technical rule but that “a decision to refuse prior authorization based on a national technical rule shall be considered to be an administrative decision” to which the Regulation applies.

Under Regulation 764/2008, the Commission had to draw up a “product list”[[46]](#footnote-46) and keep up to date a non-exhaustive list of products which are not subject to EU harmonisation legislation[[47]](#footnote-47). That list - necessary to apply the principle in practice - is not reliable since it has not been regularly updated and has not given any information on partially harmonised products[[48]](#footnote-48). No provision regarding this list is clearly a miss within the Regulation. It is only briefly mentioned in the recitals[[49]](#footnote-49) that the Commission will assess the feasibility and benefits of further developing an indicative product list. Should there not be a legal obligation upon the Commission to update the list every 6 months instead? Without such a list, it is likely that the clarifications regarding the Regulation’s scope will only partially address the legal uncertainty businesses and national authorities face on a daily basis as regards the scope of mutual recognition.

1. ***Increasing legal certainty as regards the application of mutual recognition and its reliability***
2. ***Mutual Recognition Declaration***

An external evaluation on the working of mutual recognition highlighted the hurdles faced by businesses when they needed to prove that their product was already on sale elsewhere in the EU in order to enjoy the benefits of mutual recognition[[50]](#footnote-50). In the food contact materials sector, which has an approximate annual turnover of €100 billion in the EU, requirement of national authorities for mutual recognition diverge significantly. For the same product, not only are requirements on declarations of conformity and supporting documents different but additional certifications are sometimes also needed. This diversity of requirements is challenging for businesses that want to sell their product in another Member State because it is difficult for them to know what to provide to national authorities[[51]](#footnote-51). In other sectors, the Commission showed that the evidence that the national authorities required range from a simple invoice to a Member State’s declaration certifying that the product has been lawfully marketed[[52]](#footnote-52).

This is where Article 4 of the Regulation should be of real help as it is intended to simplify the procedures for businesses about the product having been lawfully marketed, or at least a greater degree than existed in the past. Article 4 provides for a Mutual Recognition Declaration (“MRD”) containing all the information necessary to carry out the assessment on whether or not the product is allowed on the market of the host State[[53]](#footnote-53). The MRD should provide for businesses a presumption that the products can be exported to the host State. The MRD is inspired from a similar declaration of compliance for harmonized products namely the EU Declaration of Conformity[[54]](#footnote-54).

An MRD is a declaration of compliance with the technical rules of the Member State where the product is being lawfully marketed (i.e the home State). It is up to the producer in the home State whether or not to use the MRD to demonstrate to the competent authorities of the Member State of destination that the goods have been lawfully marketed in another Member State[[55]](#footnote-55). Producers must follow the structure set out by the Regulation in its annexes[[56]](#footnote-56). They must draw up their declaration in one of the Union’s official languages and translate it if the Member State of destination requests it[[57]](#footnote-57). Alternatively, where the producer is only able to provide the information on the lawfulness of the marketing of the goods in the declaration, the latter may be drawn up by the importer or by the distributor[[58]](#footnote-58). Moreover, economic operators are responsible for the content and accuracy of the information that they provide[[59]](#footnote-59). The declaration must be kept up-to-date at all times[[60]](#footnote-60). Finally, they have the possibility to make their declaration available online[[61]](#footnote-61).

Another apparent advantage of the MRD is that it is a “single standardized document”[[62]](#footnote-62) replacing countless documents demanded by national authorities and that differ between Member states, leaving businesses uncertain about what documents they needed to provide[[63]](#footnote-63). The MRD should, in principle, therefore help economic operators to prove that a product is being lawfully marketed in the host State.

But the MRD raises a number of issues that may not lead to its intended benefits being realised.

It is true that by choosing a voluntary-based system, the Regulation avoids a mandatory-based legislation, which could become a heavy burden on businesses in practice[[64]](#footnote-64). However, the MRD and Article 4 only work positively for business if both businesses and the national authorities are fully aware of the functioning of the mutual recognition framework and this is unlikely to be the case.

The MRD is unlikely to work properly because its success strongly relies on future awareness-raising policies. Since there is still an important lack of awareness among the business community and national authorities about the mutual recognition system and how it functions in practice, the effectiveness of Article 4 is undermined.

In fact it seems that only large companies exporting to other Member States seem to have an idea of what the mutual recognition principle is, while SMEs often do not[[65]](#footnote-65). This is problematic since around 87% of the enterprises operating within the non-harmonised sectors are micro enterprises (i.e. with less than 9 employees) and around 11% are small and medium enterprises[[66]](#footnote-66). Furthermore, most businesses regardless of their size are used to checking the national requirements of the host State and adapting their products accordingly before entering a market and do not consider whether the mutual recognition principle might apply[[67]](#footnote-67). If businesses do not understand the principle of mutual recognition, it is not surprising that they do not use the facility offered by the MRD and Article 4.

Most national authorities of course assume that they know and understand the principle of mutual recognition and how it works and they need to have that understanding as they are the recipients of the MRDs. However, Product Contact Points[[68]](#footnote-68) disagree on the level of awareness of national authorities. They highlighted that several sectors remain problematic due to the lack of awareness by national authorities with national authorities at regional and local levels being particularly less familiar with the principle of mutual recognition[[69]](#footnote-69).

The question stemming from these facts is the following: how will the national authorities deal with the MRD? Although the question cannot be answered today, the lack of knowledge from competent authorities (especially the regional and local ones) might seriously undermine the objective of Article 4.

Moreover, it is likely that SMEs will not provide a MRD since many of them do not know and understand the mutual recognition principle[[70]](#footnote-70). Where a MRD is not provided, national authorities can insist upon the provision of all the documentation and information they deem necessary[[71]](#footnote-71). Ex-post evaluation of Regulation 764/2008 has shown that national authorities often deny market access although businesses may be relying legitimately on mutual recognition[[72]](#footnote-72). There is a strong risk that national administrations keep asking for unnecessary documents when a MRD is not provided. This is particularly true in some specific sectors where the lack of trust is very strong, e.g. fertilizers where most Member States express a strong reluctance to accept mutual recognition due to environmental and human health concerns[[73]](#footnote-73). The risk of illegitimate or disproportionate administrative decision remains unresolved when a business does not use the MRD.

In light of the above reasons, it is likely that Article 4 will unleash its full potential only when all stakeholders become aware of what mutual recognition really means. It should also be noted that awareness-raising policies must particularly focus on SMEs and on regional and local authorities. If they do not, the provision might benefit only large companies.

1. ***Assessment of goods and temporary suspension of market access***

Article 5 of the Regulation lays down the new procedure to be followed by national authorities when assessing if goods lawfully marketed in another Member State can be marketed on their territory on the basis of mutual recognition. The procedure is of strategic importance since national administrations need to follow its every step. The procedure would also eliminate existing hurdles faced by businesses. In the food supplements sector, especially when it comes to food enrichers such as vitamins, economic operators often complain about having their products denied based on public safety issues without transparency[[74]](#footnote-74). To businesses, national authorities tend to focus on national legislation when deciding, without taking into account other Member States’ certifications or proof of the fact that the product is already lawfully marketed in another Member State[[75]](#footnote-75).

When a national authority intends to assess goods subject to the Regulation, it must contact the economic operator without delay[[76]](#footnote-76) and also inform that person or entity of the possibility of providing a MRD[[77]](#footnote-77). The provision gives businesses the right to make the goods available on the market in the Member State of destination even while the competent authority carries out the assessment of the product[[78]](#footnote-78). The economic operator also has the right to submit comments as part of the assessment process [[79]](#footnote-79). The competent authority’s room for manoeuvre in its assessment is therefore determined by whether or not the MRD is provided[[80]](#footnote-80). The competent authorities in Member States of destination must take into account any test reports or certificates issued by a conformity assessment body that have been provided by an economic operator[[81]](#footnote-81). Moreover, the provision requires the national authorities to give a detailed and reasoned decision, including some mandatory information[[82]](#footnote-82). Finally, the administrative decision regarding the assessment of the goods must specify the remedies available under the national law of the Member State of destination if approval is refused and the time limits for bringing such proceedings with a reference to SOLVIT[[83]](#footnote-83).

Article 5 has two great potential benefits for businesses. First, it allows businesses to start selling their products while the competent authority carries out the assessment on their products, with suspension of that right only being allowed in certain limited circumstances (as set out in Article 5(3) and Article 6 – see below).

However, this right to sell during the assessment period is itself limited by the two further provisions in the Regulation.

First, Article 5(3) provides that businesses cannot rely upon the provision where the assessment is carried out in the framework of a prior authorisation procedure[[84]](#footnote-84). Despite the fact that businesses ranked these procedures second as obstacles to effective mutual recognition[[85]](#footnote-85), the legal uncertainty surrounding prior authorisation procedures will remain unchanged. Member States may use these procedures to delay the approvals of products that are due to enter the market, the main consequence of this is that SMEs with products of low added values (such as fertilizers) will end up not entering the market[[86]](#footnote-86).

Second, Article 5(3) also provides that the right to market goods during the assessment period may be suspended under the conditions set out in Article 6.

Article 6 provides the temporary suspension of goods lawfully marketed in another Member State. Goods may only be ordered if “*(a) under normal or reasonably foreseeable conditions of use, the goods pose a serious risk to safety or health of persons or to the environment, including one where the effects are not immediate, which requires rapid intervention by the competent authority; or (b) the making available of the goods, or of goods of that type, on the market in that Member State is generally prohibited in that Member State on grounds of public morality or public security”*[[87]](#footnote-87).

However Article 6(2) provides that a temporary suspension under Article 6(1) can only be imposed on the basis of a detailed technical or scientific justification demonstrating why the product poses such serious risk - so a hark back to the Court of Justice’s well-established case law regarding the use of derogations to the free movement goods[[88]](#footnote-88). Although Article 6 has not been applied yet, there is nevertheless the risk that host Member States will abuse this provision in order to prevent a business from selling its product during the assessment process. National administrations must also of course comply with the principle of proportionality and therefore the principle of good administration stemming from it. Even so, the Court of Justice’s recent case-law shows that it is not yet fully respected by all Member States in all sectors[[89]](#footnote-89). How national administrations will apply the power given them to suspend temporarily the marketing of goods on their territory therefore remains uncertain.

Article 5(3) read in conjunction with Articles 6(1) and (2) is a careful balancing act between the interest of business and the free movement of goods and the duties of Members States to be able to protect the State and citizens against certain risks. It does this on the one hand by taking away the power of the host State to control the marketing of goods during the assessment phase but on the other then partially restoring that power by permitting a temporary power of suspension in certain limited circumstances and subject to proper evidential proof of the need for a suspension. Meanwhile, what remains unchanged is the level of trust among Member States. Thus, in this context of lack of trust where host Member States have their influence greatly reduced in decision making, it is very likely that Article 6 ends up misused and prevent businesses from selling their product while the assessment is carried out by competent authorities.

The possible need for having resort to the national courts to ensure the right to market goods during the assessment period is perhaps underlined by the widespread disregard of the Member States of their obligation (also under Article 6(2) of the Regulation) to notify the Commission of any temporary suspension; only a few Member States – in fact almost exclusively Portugal - communicated their administrative decisions to deny market access in the past under Regulation 764/2008[[90]](#footnote-90). It is not clear why the position should change for the future under the Regulation as there is no effective sanction when a Member State does not notify. A powerful incentive could be drawn from what is done in the *ex-ante* stage under Directive 2015/1535. If a national provision is not notified under the Directive as required by the legislation the national provision can be declared inapplicable by national courts[[91]](#footnote-91). The draw back to this kind of court based system is that it is a costly and lengthy process for businesses, the optimum solution for business being of course that non notification leads *automatically* to the inapplicability of the national measure – here to the decision of the national authority denying the right to put the product on the market.

In light of the above observations regarding Article 6, it is legitimate to doubt its smooth application by Member States. It is likely that Member States will misuse the provision, especially in problematic sectors[[92]](#footnote-92) where the lack of trust between competent authorities is high[[93]](#footnote-93) – therefore preventing businesses from enjoying their rights provided in Article 5. In a context permeated with such lack of trust, it is hard – if not impossible – to bring legal certainty.

The second achievement concerns the procedural guarantees within Article 5 paragraphs 10 and 11 ensuring that Member States use their right to deny mutual recognition in the light of the proportionality principle, thus bringing more legal certainty. The Regulation incorporates the Court of Justice’s well-established case law regarding the use of derogations on free movement of goods[[94]](#footnote-94) by requiring a detailed technical or scientific justification.

But is the internal logic of the Regulation structured so that the burden of proof lies on the national authority to show there are legitimate public interest grounds to justify the application of its national technical rules and accordingly deny the market access to the market?

Although Article 5(4)(a) of the Regulation lays down what a competent authority may do in its assessment when there is a MRD, the effective burden of proof depend on the interpretation by national authorities of the key provision “*together with supporting evidence necessary to verify the information contained”*[[95]](#footnote-95) in the MRD. There is a risk that national authorities ask excessive information and documents that unlawfully delay market access. Whilst the Regulation requires the national authorities to provide the reasons and evidence relied upon by it to deny a product access to the market[[96]](#footnote-96), in practice, the national authority might shift the burden of proof through the way they run the assessment process to businesses in effect having to demonstrate that their products are not dangerous and especially in the light of the technical and scientific evidence the national authority itself has and may wish to rely upon, as to which see Article 5(11)(c) (and in such a way that it limits their ability to challenge the decision of the national authorities, considering time and resources needed, as it was the case under Regulation 764/2008[[97]](#footnote-97)). This potential risk may of course be mitigated by the new guidance on the concept of “lawfully marketed”[[98]](#footnote-98), combined with awareness-raising policies.

The second reason is that there is a risk that companies continue to comply with national requirements although they could benefit from mutual recognition by challenging illegitimate or disproportionate administrative decisions. Despite the need under Article 5 (10) and (11) of the Regulation for the national authorities to fully reason their decisions will assist business to challenge them, legal challenges to an administrative decision are inevitably daunting. It requires the business to enter into a time consuming and costly exercise and with the outcome often far from certain[[99]](#footnote-99). Moreover businesses may fear that challenges may affect the way the national authorities will decide other cases concerning their products. Somewhat ironically therefore, since the provisions in the Regulation intended to make challenges easier cannot achieve that in many cases without changes to the appeal system itself, business have either adapted their products to the meet the national standards, so the reverse of mutual recognition, or abandoned entering the market and that mutual recognition was intended to facilitate[[100]](#footnote-100)

1. ***New problem-solving procedure (SOLVIT[[101]](#footnote-101))***

Recognising the unwillingness of businesses to challenge administrative decisions through the normal court procedure, the Regulation has put in place a ‘new’ and non judicial procedure for challenging administrative decisions denying market access[[102]](#footnote-102). The procedure has two steps. First, a business may challenge a national decision in an informal way through the existing network SOLVIT. The Commission during this step may upon request informally assist SOLVIT with the necessary technical expertise. Second, when no solution is found between the economic operator, the national authority and SOLVIT, the latter may request the Commission to give an opinion on the case[[103]](#footnote-103). The Commission has 45 working days to issue its opinion[[104]](#footnote-104).

This new procedure seems at first to answer the needs of economic operators[[105]](#footnote-105). In following the SOLVIT route, they would avoid the costs usually related to court proceedings (SOLVIT is free of charge), reduce significantly costs linked to adapting their products to meet the host market rules, and perhaps obtain quicker access to the host market thereby also avoiding lost opportunities[[106]](#footnote-106). It would seem especially useful for SMEs in the non-harmonised sectors since they do not have the resources to go to court. Moreover, the Commission’s opinion “would be a powerful deterrent”[[107]](#footnote-107) to national authorities when they unlawfully deny market access.

But SOLVIT has its limitations, exemplified by its very low usage (only 5 cases relating to mutual recognition in 2016[[108]](#footnote-108)). The Commission itself has observed that “demonstrating that a particular national restrictive measure is unjustified would require technical expertise and formal powers that SOLVIT centers do not enjoy nowadays”[[109]](#footnote-109). So why has the Commission based its new non judicial procedure for challenging national decisions on a pre-existing network that has not proved to be an effective solution in the past and that seems to have such a fundamental flaw in it through not having the necessary technical expertise and powers to discharge its functions and provide a proper remedy, even if only on an “advisory” basis to businesses? Indeed the Commisison does not express optimism about the future of SOLVIT as it speaks of SOLVIT still having "limitations in offering efficient remedies for challenging unjustified decisions denying market access. Furthermore, without providing for the Commission technical assistance and further involvement for the goods cases, it is not expected that SOLVIT will produce better results for these cases as compared to the current situation”[[110]](#footnote-110).

1. **CONCLUSION**

There is a paradox in “mutual recognition” that Maduro has described as “the greater the initial degree of policy or systemic divergence, the greater the likelihood that mutual recognition will face resistance and the greater the justification to impose on a state the recognition of the other’s policies. The paradox is that it is also where divergence is greater that mutual recognition is more needed as an instrument for economic and political integration”[[111]](#footnote-111).

With the Regulation, the EU legislator has tried to overcome Regulation 764/2008’s failure and enhance the mutual recognition’s framework. While the scope of products covered has been improved and the procedure for businesses to prove that a product was lawfully marketed has been simplified, the key to achieving real mutual recognition is unwinding “the policy and systemic divergences” between Member States referred to by Maduro. That is more a cultural change by trusting the national standards of other Member States than one resolved by legislative means.

Until that occurs host Member States will keep trying to retain control over goods on their territory, and derogations from the Treaties and the Regulation will not be used correctly. Member States can fairly have doubts regarding certain products but this does not mean they can use derogations to mutual recognition because they do not share the same regulatory culture. One of the Regulation’s aims is to discipline Member States in their recourses to mutual recognition’s derogations, but it might not be strong enough to make host Member States refrain from doing so.

1. See for a detailed review on this topic, M Maduro ‘So close and yet so far: the paradoxes of mutual recognition’ (2007) Journal of European Public Policy 814; SK Schmidt ‘Mutual recognition as a new mode of governance’ (2007) Journal of European Public Policy 667; C Janssens, *The Principle of Mutual Recognition in EU Law* (5th edn, Oxford University Press, 2013); K Nicolaïdis ‘Trusting the Poles? Constructing Europe through mutual recognition’ (2007) Journal of European Public Policy 682. [↑](#footnote-ref-1)
2. European Commission, *Impact assessment accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the mutual recognition on goods lawfully marketed in another Member State* (SWD 2017 471) 5. [↑](#footnote-ref-2)
3. European Commission, *The Single market in a changing world* (COM 2018, 772). [↑](#footnote-ref-3)
4. European Commission, *Technical harmonisation and standards: a new approach* (1985, P/85/12). [↑](#footnote-ref-4)
5. Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation [2012] OJ L316. [↑](#footnote-ref-5)
6. European Commission, *Analysis of the implementation of the Regulation (EU) No 1025/2012 from 2013 to 2015 and factsheets* (COM 2016, 212 final) 23-25. [↑](#footnote-ref-6)
7. “Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States”. [↑](#footnote-ref-7)
8. “The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States”. [↑](#footnote-ref-8)
9. Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon)* [1979] ECLI:EU:C:1979:42, para. 14. [↑](#footnote-ref-9)
10. Case 302/86 *Commission* v. *Denmark* [1988] ECLI:EU:C:1988:421. [↑](#footnote-ref-10)
11. Case 120/78 *Cassis de Dijon* [1979] ECLI:EU:C:1979:42. [↑](#footnote-ref-11)
12. Joined Cases C-267/91 *Criminal Proceedings Against Bernard Keck and Daniel Mithouard* [1993] ECLI:EU:C:1993:905,para. 15. [↑](#footnote-ref-12)
13. “Around 87% of the enterprises operating within the non-harmonised sectors are micro enterprises (i.e. with less than 9 employees) and around 11% are small and medium enterprises (i.e. with a number of employees between 50 and 250)”. European Commission, supra, note 2, 12. [↑](#footnote-ref-13)
14. Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification) [2015] OJ L241. [↑](#footnote-ref-14)
15. Art. 5 of Directive 2015/1535. [↑](#footnote-ref-15)
16. Art. 34 TFEU. [↑](#footnote-ref-16)
17. European Commission, *Study on the costs and benefits of the revision of the Mutual Recognition Regulation (EC)* No764/2008 (2017) 33. [↑](#footnote-ref-17)
18. European Commission, *REFIT evaluation accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the mutual recognition on goods lawfully marketed in another Member State* (SWD 2017, 475 final) 24. [↑](#footnote-ref-18)
19. “Since the New Approach calls for common essential requirements to be made mandatory by legislation, this approach is appropriate only where it is possible to distinguish between essential requirements and technical specifications. Further, as the scope of such legislation is risk-related, the wide range of products covered has to be sufficiently homogeneous for common essential requirements to be applicable. The product area or hazards also have to be suitable for standardisation” European Commission, *The ‘Blue Guide’ on the implementation of EU products rules 2016* [2016] OJ C272. [↑](#footnote-ref-19)
20. European Commission, supra,note 17, 63. [↑](#footnote-ref-20)
21. European Commission, supra,note 2, 45. [↑](#footnote-ref-21)
22. European Commission, supra, note 18, 67. [↑](#footnote-ref-22)
23. Idem. [↑](#footnote-ref-23)
24. Idem. [↑](#footnote-ref-24)
25. European Commission, supra, note 18, 176. [↑](#footnote-ref-25)
26. M Maduro ‘So close and yet so far: the paradoxes of mutual recognition’ (2007) Journal of European Public Policy 814, 815. [↑](#footnote-ref-26)
27. Idem. [↑](#footnote-ref-27)
28. Idem. [↑](#footnote-ref-28)
29. SK Schmidt ‘Mutual recognition as a new mode of governance’ (2007) Journal of European Public Policy 667, 672. [↑](#footnote-ref-29)
30. Idem. [↑](#footnote-ref-30)
31. C Barnard, *The Substantive Law of the EU: The Four Freedoms* (5th edn, Oxford University press, 2016) 150. [↑](#footnote-ref-31)
32. Ibid., 172. [↑](#footnote-ref-32)
33. European Commission, supra, note 18, 7. [↑](#footnote-ref-33)
34. Ibid., 81. [↑](#footnote-ref-34)
35. European Commission, supra, note 17, 56; European Commission, supra, note 18, 177. [↑](#footnote-ref-35)
36. “As regards businesses, the main costs incurred are triggered by the need to adapt the products to the applicable national rules, when mutual recognition is either denied or not used for penetrating the market. These costs are estimated on average at 23 000 Euro per product and per market. High costs are also related to delays in entering a market, estimated at 115 000 Euro per product and per market, and to lost opportunities, when businesses relinquish entering a market because of different national rules that require their products to be adapted. On average, the latest are estimated at 136 000 Euro per product and per market. The costs related to challenging administrative decisions denying market access are considered as less important, mainly because few economic operators choose to do so. The estimates are around 32 000 Euro per product and per market. There are however considerable variations in the answers”. European Commission, supra, note2, 74-75. [↑](#footnote-ref-36)
37. European Parliament, *Briefing document*: *mutual recognition of goods*, European Parliamentary Research Service (2019) 4-5. [↑](#footnote-ref-37)
38. European Commission, *The Goods Package: Reinforcing trust in the Single Market* (COM 2017, 787 final). [↑](#footnote-ref-38)
39. Ibid., 7. [↑](#footnote-ref-39)
40. European Commission, *Upgrading the Single Market: more opportunities for people and business* (COM 2015, 550 final). [↑](#footnote-ref-40)
41. European Commission, supra, note 2, 31. [↑](#footnote-ref-41)
42. “During the 2016 public consultation, 84% of Member States, 85% of businesses and 82% of citizens supported this option”. European Commission, supra,note 2,37. [↑](#footnote-ref-42)
43. Art. 2 Regulation (EC) 764/2008. [↑](#footnote-ref-43)
44. Art. 2(2)(a) Regulation (EU) 2019/515. [↑](#footnote-ref-44)
45. “A prior authorisation procedure is an administrative procedure established by the legislation of a Member State in accordance with which, before a product may be placed on that Member ﻿State's market, the competent authority of that Member State must give formal approval following an application”. European Commission, supra, note 18, 166. [↑](#footnote-ref-45)
46. <https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/products-list\_en>. [↑](#footnote-ref-46)
47. Art. 12(4) Regulation (EC) 764/2008. [↑](#footnote-ref-47)
48. “In 2015, for example, the web-page hosting the product list received 2655 visits, and 59% of them left the page immediately, without trying to use the list”. European Commission, supra, note 18, 35. [↑](#footnote-ref-48)
49. Recital (12) of Regulation (EU) 2019/515 : “In order to help to identify which types of goods are subject to this Regulation, the Commission should assess the feasibility and benefits of further developing an indicative product list for mutual recognition”. [↑](#footnote-ref-49)
50. European Commission, supra, note 18, 62. [↑](#footnote-ref-50)
51. European Commission, supra, note 2, 137. [↑](#footnote-ref-51)
52. European Commission, *The Goods Package: Reinforcing trust in the Single Market* Brussels (COM 2017, 787 final) 8. [↑](#footnote-ref-52)
53. European Commission, supra, note 2, 37-38. [↑](#footnote-ref-53)
54. E.g. Directive 2009/48/EC on the safety of toys [2009] OJ L170. [↑](#footnote-ref-54)
55. Art. 4(1) al.1er Regulation (EU) 2019/515. [↑](#footnote-ref-55)
56. Art. 4(1) al.3 Regulation (EU) 2019/515. [↑](#footnote-ref-56)
57. Art. 4(1) al.6 Regulation (EU) 2019/515. [↑](#footnote-ref-57)
58. Art. 4(1) al.4 and Recital 18 Regulation (EU) 2019/515. [↑](#footnote-ref-58)
59. Art. 4(2) Regulation (EU) 2019/515. [↑](#footnote-ref-59)
60. Art. 4(3) Regulation (EU) 2019/515. [↑](#footnote-ref-60)
61. Art. 4(5) Regulation (EU) 2019/515. [↑](#footnote-ref-61)
62. European Commission, supra, note 2, 37-38. [↑](#footnote-ref-62)
63. European Commission, supra, note 18, 128. [↑](#footnote-ref-63)
64. “On the contrary, a mandatory Declaration of Compliance in the non-harmonised area would be an administrative burden for economic operators, as economic operators would have to draft it and present it no matter what, even for simple products where there are no (or few) applicable national rules and therefore no real need for such a declaration and no real added value in terms of facilitating dialogue and market access”.

    European Commission, supra, note 2, 49. [↑](#footnote-ref-64)
65. “More than a third of the product contact points assess that among SMEs seeking to market a product in another Member State, less than 25% know and understand the mutual recognition principle, while 40% of product contact points believe that only between 25% and 50% of SMEs know and understand the principle”. European Commission, supra, note 18, 142-143. [↑](#footnote-ref-65)
66. European Commission, supra, note 2, 12. [↑](#footnote-ref-66)
67. European Commission, supra, note 18, 192. [↑](#footnote-ref-67)
68. The Product Contact Point is the contact for the economic operator for questions pertaining to the application of the mutual recognition principle. Each EU Member State is required to establish a Product Contact Point. Through information on national rules and remedies, the Contact Points help reduce the risk that a product is unlawfully denied access to a market of another EU Member State. [↑](#footnote-ref-68)
69. European Commission, supra, note 18*,* 157-159. [↑](#footnote-ref-69)
70. European Commission, supra, note 2, 142-143. [↑](#footnote-ref-70)
71. Art. 5(3) Regulation (EU) 2019/515. [↑](#footnote-ref-71)
72. European Commission, supra, note 18. [↑](#footnote-ref-72)
73. Commission Proposal for a Regulation of the European Parliament and of the Council laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 (COM 2016, 157). [↑](#footnote-ref-73)
74. European Commission, supra, note 18, 115. [↑](#footnote-ref-74)
75. Ibid., 114. [↑](#footnote-ref-75)
76. Art. 5(1) Regulation (EU) 2019/515. [↑](#footnote-ref-76)
77. Art. 5(2) Regulation (EU) 2019/515. [↑](#footnote-ref-77)
78. Art. 5(3) Regulation (EU) 2019/515. [↑](#footnote-ref-78)
79. Art. 5(6) Regulation (EU) 2019/515. [↑](#footnote-ref-79)
80. Art. 5(4) and (5) Regulation (EU) 2019/515. [↑](#footnote-ref-80)
81. Art. 5(8) Regulation (EU) 2019/515. [↑](#footnote-ref-81)
82. Art. 5(10) and (11) Regulation (EU) 2019/515. [↑](#footnote-ref-82)
83. Art. 5(12) Regulation (EU) 2019/515. [↑](#footnote-ref-83)
84. National technical rules are sometimes given effect in a Member State by means of a prior authorisation procedure, under which formal approval has to be obtained from a competent authority before the goods can be placed on the market there. [↑](#footnote-ref-84)
85. European Commission, supra, note 18, 168. [↑](#footnote-ref-85)
86. Ibid.,166. [↑](#footnote-ref-86)
87. Art. 6(1) Regulation (EU) 2019/515. [↑](#footnote-ref-87)
88. E.g. C-672/15 *Procureur de la République v Noria Distribution SARL* (2017) ECLI:EU:C:2017:310, para. 49 ; Case C-320/03 *Commission v. Austria* *(heavy lorries)* [2005] ECLI:EU:C:2005:684. [↑](#footnote-ref-88)
89. Seein the food supplements sector: Case C-672/15 *Procureur de la République v Noria Distribution SARL* [2017]ECLI:EU:C:2017:310. See also B. Jan ‘Mutual recognition failure in the light of free movement of food supplements: Judgement of the CJEU, 27 April 2017, Noria Distribution SARL’ (2018) Legal issues of economic integration 311. [↑](#footnote-ref-89)
90. “In the period between the entry into force of the Regulation 764/2008 on 13 may 2009 and today, the Commission has received 3918 notifications. All notifications received come from 6 Member States, and one Member State, namely Portugal, accounts for around 80% of the notifications received”. European Commission, supra, note 18, 35. [↑](#footnote-ref-90)
91. Case C-194/94 *CIA Security International SA v Signalson SA and Securitel SPRL* (1996) ECLI:EU:C:1996:172. [↑](#footnote-ref-91)
92. E.g. Fertilizers, food labelling, food supplements, construction products and hallmarks. European Commission, supra, note 18, 23. [↑](#footnote-ref-92)
93. Ibid., 187. [↑](#footnote-ref-93)
94. E.g. Case C-95/01 *Greenham and Abel* (2004) ECLI:EU:C:2004:71. [↑](#footnote-ref-94)
95. Art. 5(4)(a) Regulation (EU) 2019/515. [↑](#footnote-ref-95)
96. Art. 5(10) and (11) Regulation (EU) 2019/515. [↑](#footnote-ref-96)
97. European Commission, supra, note 18, 35-37. [↑](#footnote-ref-97)
98. European Commission, *Guidance document: ‘The concept of ‘lawfully marketed’ in the Mutual Recognition Regulation (EC) No 764/2008* (COM 2013, 592 final). [↑](#footnote-ref-98)
99. European Commission, supra, note 18, 52. [↑](#footnote-ref-99)
100. Idem. [↑](#footnote-ref-100)
101. SOLVIT is a service provided by the national administration in each Member State that aims to find solutions for individuals and businesses when their rights have been breached by public authorities in another Member State. The principles governing the functioning of SOLVIT are set out in Commission Recommendation 2013/461/EU according to which each Member State is to provide for a SOLVIT Centre that has adequate human and financial resources to ensure that the SOLVIT Centre takes part in SOLVIT. [↑](#footnote-ref-101)
102. Art. 8 Regulation (EU) 2019/515. [↑](#footnote-ref-102)
103. Art. 8 para. 1 Regulation (EU) 2019/515. [↑](#footnote-ref-103)
104. Art. 8 para. 4 Regulation (EU) 2019/515. [↑](#footnote-ref-104)
105. “When asked to rank obstacles to mutual recognition by order of importance , the difficulty in challenging administrative decisions denying or restricting market access was considered as the main obstacle by businesses (62% of businesses responding to the 2016 public consultation), and 72% considered that ensuring effective remedies for taking action against such decisions should constitute the Commission's main priority”. European Commission, supra, note 2, 23. [↑](#footnote-ref-105)
106. “Adaptation costs were estimated between 1000 and 150 000 Euro per product and per market. Delays for entering a market were estimated between 3000 and 500 000 Euro per product and per market, and lost opportunities, were estimated between 10 000 and 500 000 Euro per product and per market”. European Commission, supra, note 18, 45-46. [↑](#footnote-ref-106)
107. European Commission, supra, note 2, 39. [↑](#footnote-ref-107)
108. Ibid., 50. [↑](#footnote-ref-108)
109. Ibid., 22. [↑](#footnote-ref-109)
110. Ibid., 30. [↑](#footnote-ref-110)
111. M Maduro ‘So close and yet so far: the paradoxes of mutual recognition’ (2007) Journal of European Public Policy 814, 822. [↑](#footnote-ref-111)