COUNTRY COMPARATIVE GUIDES 2021

The Legal 500 Country Comparative Guides

Spain

PRODUCT LIABILITY

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This country-specific Q&A provides an overview of product liability laws and regulations applicable in Spain.

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SPAIN
PRODUCT LIABILITY

1. Please summarise the main legal bases for product liability

In Spain, the general liability for defective products regime is established in Royal Legislative Decree 1/2007, of 16 November, which approves the consolidated text of the General Law on the Protection of Consumers and Users and other complementary regulations ("RDL 1/2007"). Articles 128 to 146 of RDL 1/2007, both inclusive, set the main rules on product liability in Spain.

The general regime for product liability set forth in RDL 1/2007 is mainly of a strict nature. Under this regime, the "producer" of a defective product will be liable for any damage caused by death or by personal injuries, and/or any damage to, or destruction of, any item of property other than the defective product itself, provided that the item of property is of a type ordinarily intended for private use or consumption and was used by the injured person mainly for his own private use or consumption. It will be on the claimant to prove that the product was defective, that damage occurred and that there was a causal link between the defective product and the damage suffered.

This strict liability system does not preclude other liability systems providing an injured party with greater protection, nor does it affect any other right to damages, including moral damages, that the injured party may have as a consequence of contractual liability, based on the lack of conformity of the goods or any other cause of non-performance or defective performance of the contract, or of any other non-contractual liability that may apply.

2. What are the main elements which a claimant must prove to succeed in a strict liability type claim for damage caused by a defective product?

The regime on product liability places the burden of proving the existence of the defect, the damage and the causal relationship between such defect and damage upon the claimant. In order to establish the causal relationship, the claimant must provide solid and substantial evidence that supports such link and that damages were an appropriate and sufficient result of the defect.

However, occasionally, the Spanish courts also accept that the causal relationship may be proven by means of presumption or circumstantial evidence.

In Spain, the principle of generic causation (i.e.: that in order to prove the causal relationship it would be enough to demonstrate that a product is capable of causing the alleged injury) is not applied. The Spanish courts have established that the mere fact that a product can cause damage is not enough to establish the defective nature of such product. In order to prove that a product is defective, the claimant must prove that the damages suffered are effectively caused by the defective product. It is sufficient that the claimant proves the existence of a defect, but it is not strictly necessary that the claimant provides evidence of the specific defect of the product. We can thus conclude that in Spain the proximate causation principle operates.

On 5 March 2015, the Court of Justice of the European Union issued a ruling on joined cases C-503/13 and C-504/13, under which certain kinds of products can be considered defective under the proximate causation principle. In these particular cases, the Court of Justice of the European Union concluded that the Directive 85/374/CEE regarding damages caused by defective products should be interpreted in the sense that, in the case of medical devices such as pacemakers and cardioverter defibrillators, considering their purpose and the vulnerability of patients who use them, the security requirements that patients can expect from such products are particularly high. Under these conditions, as they are products of the same model and production series, after a defect has been detected in a unit, the other units of the same model or batch can be classified as defective without being necessary to prove the existence of the defect in each of the units.

On 21 June 2017, the Court of Justice of the European

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Union issued another case (C-621/15) referring to product liability of manufacturers in the event that their products have a defect which poses a risk to the consumer. The Court, in these circumstances, decided that European law does not preclude a national court to consider, when medical research does not establish nor reject a relationship between the vaccine and the occurrence of a disease, that some facts alleged by the injured person constitute serious specific and consistent evidence, enabling the court to conclude that there is a defect in the vaccine and that there is a causal link between that defect and the disease.

On the other hand, the Court also ruled that judges should ensure that when applying this evidence regime, they do not reverse the burden of proof. According to the Court, the directive precludes rules based on presumptions in which medical research neither establishes nor rules out existence of a link between the vaccine and the disease, the existence of a causal link between the defect attributed to the vaccine and the damage suffered by the affected party will always be considered established if certain predetermined factual evidence is presented.

In the five Judgements issued between 2017 and 2019 by the National High Court ("AN") regarding different liability claims filed in connection with human papillomavirus vaccines, the court confirmed that the burden of proving the defect, the damage and the causal relationship lies with the claimant and, in the absence of evidence from the claimant, it absolved the MOH and the pharmaceutical company of all wrongdoings attributed to them.

The AN rejected the evidence proposed by the claimants consisting of opinions which, according to the court, did not undermine the studies and clinical trials that endorsed the efficacy of the product.

With respect to the alleged lack of informed consent prior to its administration, the AN rejected the complaints because claimants had not demonstrated that the pathologies they were diagnosed with were a frequent adverse reaction, and therefore the obligation to inform did not include such risk since it was not known.

Moreover, the AN considered that the causal relationship between the diagnosed diseases and the vaccines had not been demonstrated, as the medical history did not associate the ailments and symptoms from which the claimants suffered with the vaccine.

The liability of the pharmaceutical companies for defect of information in the Summary of Product Characteristics and the leaflet was also rejected because the claimants had not proved that their diseases were caused by the vaccine.

3. With whom does liability sit? If there is more than one entity liable, is liability joint and several?

For the purposes of this regime "producer" means: (i) the manufacturer or the importer in the European Union of a finished product, any raw material, or a component part of the finished product; and/or (ii) the "apparent producer" of the product (i.e.: any person who, by putting his name, trademark, or other distinguishing feature along with the product, whether on the container, wrapping or any other protective or presentational component, presents himself as its producer).

The "producers" responsible for the same damage by application of this regime will be jointly and severally liable before the injured party. However, the one who responded to the injured party will have the right to file an action for recovery against the other responsible "producers", according to their participation in the damage.

Where the "producer" of a product cannot be identified, each supplier of this product (i.e. the distributor or the "retail" supplier) will be considered as its "producer", unless he informs the injured party of the identity of the "producer" or of the person who supplied him with the product, within a term of three months before he is required to give such information. This has been clarified, among others, by the Judgment of the European Court of Justice of 2 January 2009 (case C-358/08) and the Judgments of the Spanish Supreme Court of 21 January 2020 and 20 of July 2020. Additionally, it must be noted that the supplier of a defective product will also respond as if he were its "producer" if he supplied the product being aware that the defects exist. In such a case, the supplier is also able to file an action for recovery against the producer.

4. Are any defences available? If so, please summarise them.

The producer shall not be liable if he can prove that the product is not defective because it provides the safety which legitimately could be expected from it, taking all circumstances into account, including the time when the product was put into circulation, the presentation of the product and the use to which it could reasonably be expected that the product would be put.

The producer shall neither be liable if he can prove:

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1. That he did not put the product into circulation.
2. That, given the circumstances of the case, it may be presumed that the defect did not exist when the product was put into circulation.
3. That the product had not been manufactured for sale or for any other form of distribution with an economic purpose, nor that it was manufactured, imported, supplied or distributed within the context of a professional or entrepreneurial activity.
4. That the defect is due to the fact that the product was elaborated in accordance with existing mandatory rules.
5. That the state of scientific and technical knowledge existing at the time the product was put into circulation did not allow for the discovery of the existence of the defect.

The producer of a part that is integrated into a finished product shall not be liable if he proves that the defect is attributable to the design of the product into which the part was integrated, or to the instructions provided by the manufacturer of the finished product.

Additionally, the doctrine points out that the apparent producer shall not be liable if he can prove that he was not the one who places the sign, brand, logo or stamp that identifies him as the apparent producer into the defective product or its packaging.

In the case of medicinal products, foods or foodstuffs intended for human consumption, the producer liable shall not be able to invoke the state of scientific and technical knowledge defense set out in point e) above.

5. What is the limitation period for bringing a claim?

The statute of limitations for proceedings claiming damages caused by a defective product under the regime of RDL 1/2007 is three years, counted from the date the damages were incurred by the injured party, provided that the identity of the party liable for the damages is known to the injured party.

The limitation period may be interrupted by the injured party by filing a claim before the courts or by means of an extrajudicial claim, or through any act of acknowledgment by the liable party.

Nevertheless, the right to claim the recovery of damages as provided in the product liability regime of RDL 1/2007 expires 10 years after the defective product was put on the market. The only way to stop this expiration date is to start legal proceedings.

6. To what extent can liability be excluded (if at all)?

Product liability cannot be excluded contractually. Any clause intended to exclude or reduce the liability system foreseen in RDL 1/2007 is ineffective against the injured party.

7. What are the main elements which a claimant must prove to succeed in a non-contractual (eg tort) claim for damage caused by a defective product?

The general torts regime is regulated in article 1902 of the Civil Code, which establishes that whoever by action or omission causes damage to another, intervening fault or negligence, will be obliged to repair the damage caused.

In claims of personal injuries caused by a defective product because the general regime of torts requires the intervention of fault or negligence by the defendant, the most common is that claimants mainly base their claims on the strict liability regime for defective product established in the RDL 1/2007. Claimants can add to this action a general tort action of the Civil Code, based on the intervention of fault or negligence, by virtue of which they are also allowed to request compensation for all those damages that are not compensable in accordance with RDL 1/2007, such as moral damages, the destruction of any property non-intended for private use, etc. (See question 1).

Broadly speaking, in order to succeed in a claim for damages based in the general torts regime, the claimant must provide the court with solid evidence that proves (i) the existence of an action or omission that generates a faulty or negligent conduct attributable to the person or entity against whom the action is directed; (ii) the existence of a damage or injury caused by that fault or negligent action or omission; and finally (iii) the causal relationship between the damage and the fault or negligent action or omission.

However, these general notes have been shaped by the case law. In this regard, the case law has pointed out that, the regulatory diligence is not sufficient to avoid general torts liability if the facts of the case show that the guarantees adopted to avoid foreseeable damages have been ineffective.

As the Spanish Supreme Court establishes in its Judgement of 7 October 1988, the general tort liability does not consist in the omission of inexcusable norms but in acting not adjusted to the due diligence required

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according to the circumstances of the specific case. Among others, in the Judgement of 14 July 2006, the Supreme Court adds that the required diligence includes both the preventions and regulatory care as well as all those that prudence imposes to prevent the harmful event, in such a way that to determine the existence of a negligent conduct, it should not only be based on personal circumstances, time and place , but also to the traffic sector or physical and social environment where the conduct is projected, to determine if the agent acted with the appropriate care, attention and perseverance, and with the necessary reflection for the damage.

Additionally, the case law of the Spanish Supreme Court has also declared that although article 1902 of the Civil Code rests on a basic guilty principle, it is not allowed to ignore that the required diligence includes not only the preventions and regulatory care, but also all those that prudence imposes to avoid the harmful event. This may lead, in some cases, into the reversal of the burden of proof and to the presumption of a negligent conduct on the defendant, as well as the application, within prudent guidelines, of risk-based liability, although without establishing it as the sole basis of the obligation to compensate. In this regard see, among other, the Judgement of the Supreme Court of 13 of July of 1999.

In relation with Judgement of 29 October 2008, the Spanish Supreme Court reminds that when a damage is produced because of the normal or abnormal exercise of an activity from which a person or company obtains an economic benefit, the burden of proof is reversed, in a way that it is not the injured party who has to prove the guilt of the person who causes the damage, rather, it is the economic agent who has to prove that he adopted all possible precautionary measures to avoid the damage.

In those cases where that presumption applies, it will be on the defendant the burden to rebottle this presumption. The defendant will bear the burden to prove its own diligence. It will not be sufficient to prove that it acted in accordance with the legal provisions, that were insufficient to prevent the damage, but also that reasonable and prudent measures were implemented to avoid such damage.

8. What types of damage/loss can be compensated and what is the measure of damages? Are punitive damages available?

Under Spanish law, no punitive damages – only compensatory damages – can be recovered. However, the courts have some discretionary powers in awarding such compensatory damages and one may expect the conduct of the defendant to have some impact on the amount of damages awarded.

Under the general torts regime, anyone who by action or omission causes damage to another, in case of fault or negligence, is obliged to repair the damage caused. This compensation may also include consequential damages (including moral damages) and loss profits.

9. How are multiple tortfeasors dealt with? Is liability joint and several? Can contribution proceedings be brought?

According to article 1902 of the Civil Code, the obligation that arises from causing damage, involving fraud or fault, is to repair the damage caused. Regarding this obligation, when there are several responsible subjects, it will be necessary to analyze whether the behavior of each of the responsible subjects can be individualized or not.

If we are facing a case of concurrence of causes in which the responsibility can be distributed among the agents to whom said causes are attributable, each responsible subject will be liable for the damage caused. However, if it is not possible to carry out such individualization and the harmful event is a joint action, formed by the cooperation of various behaviors, all subjects will be jointly and severally liable for the harmful event.

10. Are any defences available? If so, please summarise them.

Under the general torts regime of article 1902 of the Civil Code, defendants can use any defense aiming to refute the liability requirements approached in question 7. In this regard, defendants may invoke:

- That they have not acted faulty or negligent. In this case the implementation of reasonable and prudent measures to avoid the causation of the damage will play a key role; or
- That the claimant has not suffered the damage that he/she claim; or
- The lack of causal relationship between the damage and the fault or negligent action or omission attributed by the claimant.

Additionally, defendants may invoke that such damages are due to:

- a force majeure event (i.e.: an extraneous event that was unforeseeable and insurmountable)
- the intervention of a third party, or

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- the fault or misconduct of the claimant

The intervention of fault or negligence by the injured party, or by a third party, may moderate or exclude the liability of the defendant in accordance with the impact of such intervention in the causation of the damage.

11. What is the limitation period for bringing a claim?

The statute of limitation for bringing a claim based in the general torts regime of the Civil Code is one year. This limitation period starts to run from the moment that the injured party has knowledge of the damages suffered and knows the identity of the person liable for such damages.

In the case of injuries, the case law tends to interpret this rule in a favorable way to the injured party, starting to count the limitation period from the moment when the injured party received the medical discharge. In the case of continuing damages, the case law has held that the prescription does not begin until the production of the definitive result.

Additionally, this limitation period can also be interrupted as previously explained in question 5.

12. To what extent can liability be excluded (if at all)?

The main specialty of torts liability compared to contractual liability is the absence of a prior obligational relationship between the agent that causes damage and the injured party. The obligation to repair the damage derives not from the breach of a contractual obligation but from the existence of an unlawful act or omission (faulty or negligent) that causes a damage to others.

The case law regarding the exclusion of torts liability is very minor in our country. The doctrine is divided between the authors who consider that torts liability cannot be excluded as it is derived from the mandatory nature of article 1902 CC and those who do not see any legal inconvenience in excluding torts liability, based on the validity of the covenants of exoneration and limitation of liability. In our opinion, applying by analogy to tort liability the principle of validity of covenants of exoneration and limitation of contractual liability can pose many difficulties.

13. Does the law imply any terms into B2B or B2C contracts which could impose liability in a situation where a product has caused damage? If so, please summarise.

Under Spanish Contract Law, anyone who during the performance of its obligations incurred in fraud or negligence, and anyone who contravenes any terms of a contract is subject to compensation for damages.

The negligent conduct consists in the omission of the diligence required by the nature of the obligation that corresponds to the circumstances of the person obliged, the time, and the place. If the obligation does not explicit the diligence to be used in its performance, the one required is the diligence of a prudent businessman.

Regarding B2B contracts, unless there is a clause to the contrary, the seller is obliged to respond for any vices or deficiencies detected in the object of the contract. With regard to B2C contracts, it is null and void and is considered ineffective any clause intended to exclude or limit: (i) the consumer or user´s right to compensation for damages caused by lack of conformity; or (ii) the agent liability in contract performance, for damages, death or injuries caused to the consumer or user due to an action or omission of the agent.

14. What types of damage/loss can be compensated and what is the measure of damages?

In contract law, compensations may include consequential damages and loss profits. If the contract establishes a valid limitation clause of liability it will be fully effective between the parties subjected to the following exceptions:

- The liability arising from fraud is enforceable in all obligations, any waiver to make it effective is always null and void (article 1102 of the Civil Code).
- The liability that comes from negligence is equally enforceable in the fulfillment of all kinds of obligations; but it may be moderated by the Courts according to the cases (article 1103 of the Civil Code).

15. To what extent can liability be excluded for contract liability (if at all)?

If the contract establishes a valid limitation clause of liability it will be fully effective between the parties subjected to the following exceptions:

- The liability arising from fraud is enforceable in all obligations, any waiver to make it

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effective is always null and void (article 1102 of the Civil Code).
- The liability that comes from negligence is equally enforceable in the fulfilment of all kinds of obligations; but it may be moderated by the Courts according to the cases (article 1103 of the Civil Code).

Any clause intended to exclude or reduce the liability system foreseen in RDL 1/2007 is ineffective against the injured party, but fully effective between B2B contracting parties, subject to the above-mentioned exceptions.

16. Are there any recent key court judgements which have had a significant impact on the approach to product liability?

Regarding medicinal product and medical devices, different judgements that deserve special mention have been issued by the Spanish Supreme Court:

Regarding the Judgement of 20 July 2020, the Supreme Court dismissed the claim brought against the distributor in Spain of a hip replacement that identifies the producer. In this Judgement, the Spanish Supreme Court highlighted that the mere fact that the producer and the distributor become part of the same company group does not imply, per se, that the distributor shall assume producer's liabilities in product liability claims. Companies of a same company group are different companies with own personality, unless they were incorporated to willful misconduct legitims rights of third parties. The potential confusion between the producer and the distributor is already solved in the regulation on product liability which imposes on distributors the obligation to identify the producer. Therefore, the distributor may only be held liable for producer's liabilities regarding defective products if the distributor does not identify the producer. If the distributor correctly identifies the producer, it shall not be held liable for any producer's liability.

On Judgements of 21 December 2020, 21 and 28 January 2021, the Supreme Court has resolved different appeals for the unification of doctrine and case law, regarding whether the Hospital that has used a product whose toxicity is discovered and alerted after it has been used, shall be liable for the injuries caused to the patient or if such liability must only rely upon the "producer" and the competent authorities that authorize such medicinal product, if applicable. The Supreme Court clarifies that, in such cases, liability must relay only upon the "producer" and, if applicable, upon the authorities that authorize such product. The Supreme Court rejects any liability from the Hospital as the competence for monitoring the adequacy of such product relied on the competent authorities (not the Hospital). The Supreme Court also points out that the Hospital can neither be held liable for the risk created by allowing the use of the product, since that risk derives from the defective manufacture of the product.

17. What are the initial litigation related steps you should take if you are facing a product liability claim or threatened claim?

If you are only the supplier or distributor of the product, the first action you must carry out is to notify the claimant, within three months of receiving the claim, your condition of supplier/distributor and the identity of the manufacturer or importer of the product in the EU if it is not identified.

If you are the manufacturer or importer in the EU of the product, the first steps you must take is checking if the claimant's action has prescribed or expired and verify if any cause of defense from liability provided in the law (see question 4) is applicable in your case.

18. Are the courts adept at handling complex product liability claims? Are cases heard by a judge or jury?

Product liability claims are heard and resolved by a Judge. To handle complex product liability claims, judges tend to rely on public scientific data, technical reports issued by regulatory authorities, experts reports, and any other evidence submitted by the parties.

In this type of proceedings, the judge may not ex officio propose the examination of expert evidence or appoint technical specialists to assess the evidence presented by the parties, but a party can request it. However, in exceptional cases, once the proceedings have been concluded and before judgment is rendered, the court may ex officio order the examination of new evidence (among which expert evidence) on relevant facts, in the event that the evidence already examined should have been insufficient. In practice, this is very unusual.

19. Is it possible to bring a product liability related group action? If so, please summarise the types of procedure(s) available

In collective legal proceedings lodged by associations or

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entities constituted for the protection of the rights and interests of consumers and users or by groups of affected people, those who have been damaged, as consumers of the product or users of the service which gave rise to the proceedings, shall be called to appear in order to assert their individual rights or interest. This call shall be made by the court, who shall announce the admission of the claim in the media with territorial coverage where the damage to these rights or interests has occurred.

When proceedings involve determined or easily determined damaged parties, the claimant or claimants must have previously notified those concerned of their intention to lodge a claim. In this case, after the call, the consumer or user may act in the proceedings at any time but may only conduct the procedural acts which have not been precluded.

When proceedings involve damages to an indeterminate number of persons or a number which is difficult to determine, the call shall suspend the course of the proceedings for a time limit which shall not exceed two months, and which shall be determined by the court in each case depending on the circumstances or complexity of the event and the difficulties concerning the determination and localisation of those damaged. The proceedings shall restart with the intervention of all the consumers who attended the call. As a rule, the individual appearance of consumers shall not be allowed subsequently, notwithstanding certain rights or interests that these may assert according to other provisions of the Code of Civil Procedure 1/2000.

20. How are cases typically funded? Can lawyers charge success fees? Is third party funding permissible?

At the end of the proceedings, the costs of the proceedings are imposed on the party who has had all his pleas rejected, unless the court considers that the case posed serious de facto or de jure doubts.

When the payment of costs is imposed on the party who has lost the case, such party shall pay all court fees and other incidental expenses, the fees of experts who have intervened in the proceedings, and, also, the fees of the attorneys of the party who has won the case, up to an amount that shall not exceed one-third of the total claimed in the proceedings for each of the litigants who have obtained such award. If the court declares the recklessness of the litigant ordered to pay, such limitation shall not apply. In the event that the pleas were partially accepted or rejected, each party shall pay the costs generated on its behalf, and half of the common costs, except when there are reasons to impose their payment upon one of the parties due to reckless litigation.

Third party funding of claims is not illegal. There is no specific provision that regulates this method apart from article 1255 of the Civil Code that set forth the following: “The contracting parties may establish any covenants, clauses and conditions deemed convenient, provided that they are not contrary to the laws, to the morals or to public policy.” Therefore, if it is not contrary to the law, morals or public order, any agreement on this regard is valid.

Lawyers are also allowed to charge a success fee if they agree so with their client. The amount of the attorney’s professional fees shall be the one freely agreed upon between the client and the attorney, in observance of the rules on ethics and on free competition. The form in which the fees are to be paid shall also be freely agreed upon and may include payment of a percentage of the outcome of the claim. However, in any case, the client shall pay the minimum expenses that the attorney may incur as a result of its designation.

Additionally, parties that provide evidence that they do not have sufficient economic resources to litigate may be beneficiaries of the legal aid to litigate if they comply with the requirements established in the Law 1/1996, of 10 January, on Legal Aid that governs the regime of access to legal aid.

21. How common are product liability claims and what factors influence their frequency?

Product liability claims are becoming more and more common.

Traditionally, our jurisdiction has not been characterized by an excessive litigation regarding damages caused by defective products. The traditional tort liability regime is a subjective liability regime that placed on them the burden of proving the guilt or negligence of the responsible party, the damage, the product defect, and the causal link.

With the incorporation of the strict liability regime for damages caused by defective products into our legal system, the burden of proof has been reduced for the injured party, which has notably burned in the increase of this type of claims.

Among the factors that increase the number of these claims, the most decisive is the notoriety of existence of a specific defect in a product. The greater the public

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dissemination of the defect of a product, the greater the number of claims that may be received.

22. What are the likely future developments in product liability law and practice? To what extent is the suitability of the law being challenged by advances in technology?

Certainly, the technological and scientific advances can have a very important impact on the practical application of the product liability law, essentially for those types of product that do not enjoy the benefit of being able to exonerate their responsibility for development risks (medicinal products, foods or foodstuffs intended for human consumption). The modification of the legal regime or the inclusion of new exoneration causes are some of the challenges that the Spanish product liability law may face due to new technological and scientific developments.

23. Please provide an update of any interesting developments which have taken place in your jurisdiction over the last 12 months.

Last 24 of December of 2020 the Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC entered into force.

The Directive contains important modifications which must be transposed no later than December 25, 2022, and the regulations resulting from such transposition must enter into force as of June 25, 2023. Therefore, important legislative initiatives must be carried out in the coming months to transpose the Directive. This may lead into significant modifications of the structure of the Spanish civil procedure.

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