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Legal considerations for digital twins in food chain scenarios

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Abstract
Digital twins offer a wide range of potential applications throughout the food supply chain, as demonstrated by the example of determining the suitability for human consumption of pre-packaged minced pork through AI-driven shelf-life assessment. As food business operators, official food control authorities and consumers are open to the use of new technology, there is currently no regulatory need for action regarding the use of AI throughout the food supply chain. However, future regulatory changes, particularly in the area of food labelling, should take into account the specific features arising from the intelligent determination of the use-by date by AI.

1 Introduction

As part of the BLE-funded "Zukunftslabor 2030" (Future Lab 2030) project, six key application scenarios for the use of digital twins along the food chain were developed using the example of pre-packaged minced pork (regarding the project itself see Fleck et al. 2025). These are referred to as "future scenarios." They address all relevant stakeholder groups, ranging from food businesses such as slaughterhouses, food manufacturers, suppliers, and retailers to official food control authorities and consumers. The future scenarios themselves are presented below, together with an assessment of their legal admissibility.

Before doing so, it is necessary to outline the general principles of food safety law in the European Union that are relevant to the project. Food that is either injurious to health or unfit for human consumption is not considered safe and may therefore not be placed on the market (cf. Art. 14 of the General Food Law Regulation (EU) No 178/2002). These strict food safety requirements are ensured through both corporate and official risk assessment of food (Art. 6 para. 2, Art. 3 No. 11 of the General Food Law Regulation). The product-specific risk assessment is on the one hand based on the available scientific evidence. On the other hand, the evaluation of suitability for human consumption has to be considered. This factor is not bound to compliance with statutory limit values—as opposed to the assessment of potential health hazards, which is not part of the project. Corporate and official decisions affecting the marketability of food are assessed by society not only against the backdrop of increasing demand for sustainability, but also in terms of ensuring the highest levels of food safety and quality (Zwieting et al. 2021). New technologies in the field of risk assessment, such as the digital twin examined here, can help to meet these requirements, particularly regarding the assessment of unsuitability for human consumption.

2 Future scenarios for food businesses

The first category comprises future scenarios related to food businesses. These affect actors such as suppliers, food retailers and manufacturers. The latter are to be understood as those that place the individual product units intended for consumers on the market.

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2.1 Intelligent estimation of the use-by date by the food manufacturer

Particularly perishable products must bear a use-by date in accordance with Art. 9 para. 1 lit. f) in conjunction with Art. 24 para. 1 sentence 1 of Regulation (EU) No 1169/2011 (in general for the legal implications of the use-bye date see Heintschel-Heinegg and Wallau 2024). The first future scenario envisages that the food manufacturer determines the use-by date by using a digital twin. This is based on all available and relevant data up to this point in time, for example on the quality of the raw materials used or on the previous compliance with cold chain requirements, which enables the display of an individually determined, dynamic date of spoilage.

Such an intelligent shelf-life indication, which does not rely on the standard storage tests typically used, is not precluded by any explicit provision of food law. This is primarily because in general there are currently no specific material requirements governing the method for determining shelf life. Moreover, imposing such a restriction on food businesses would be incompatible with fundamental principles of food law – particularly the primary responsibility of the business under Article 19(1) of Regulation (EC) No 178/2002. Other specific food regulations, such as Regulation (EU) No 2024/1689, also do not contain any provisions that would prevent the application of such an intelligently developed use-by date. Accordingly, the scenario can be implemented within the current legal framework.

2.2 Support of corporate self-monitoring and process monitoring

In addition, food business operators (FBO) can use the digital twin to support their self-monitoring systems and process monitoring – for example, by comparing the actual quality status of incoming and outgoing goods with the data documented in the digital twin.

From a legal point of view, the use of the digital twin is unproblematic both to improve self-monitoring and process monitoring. This applies in particular to measures taken voluntarily by the food business operator in addition to its legal obligations. The food business also has a certain amount of leeway when it comes to meeting binding requirements regarding self-monitoring. For example, in the case of the establishment and implementation of self-monitoring systems in accordance with the principles of the HACCP concept under Article 5 para. 1 of Regulation (EC) No 852/2004, it can determine the specific implementation modalities under its own responsibility. The same applies to the examination of compliance with limit values from Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs. This regulation explicitly opens up the possibility for food businesses to use methods other than the reference methods, even for food safety and process hygiene criteria, in particular faster methods, as long as they provide equivalent guarantees of food safety (recital 24). Moreover, the determination of fitness for consumption is not governed by fixed legal requirements as to the method to be applied. The requirements of Regulation (EC) No 853/2004, which contains specific hygiene rules for food of animal origin, also leave the food business operator room for maneuver in practical implementation (cf. recital 19). On this basis, the use of the digital twin is also permissible for the fulfilment of such legal requirements.

2.3 Intelligent cold chain management

The third and most prominent food business scenario concerns the use of the digital twin in the event of an interruption in the cold chain. According to Section V, Chapter III No. 2 c) i) of Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, immediately after production a core temperature of 2 degrees must be maintained during storage and transport. The data stored and analyzed in the digital twin can be used in the case of a temporary breach of the required storage temperature to decide whether the printed shelf-life information is still valid.

If this assessment results in a need for an adjustment of the date labeling, the question arises as to whether an entity downstream of the manufacturer – such as a retail business – may change the use-by date originally printed by the manufacturer in accordance with food labelling regulations. In this respect, Art. 8 para. 4 of Regulation (EU) No 1169/2011 (FIC Regulation) is decisive, according to which such an amendment may not be misleading or reduce the level of consumer protection in any other way. However, a potential misleading effect can be avoided by a clarifying note that states both the identity of the entity making the change and the nature of the change in a comprehensible manner (Korthals Altes 2025). Accordingly, the current legal framework already provides a sufficient legal basis for addressing this scenario. At present, there appears to be no need for a specific legislative provision explicitly regulating the amendment of use-by dates based on digital twin assessments.

A scenario in which manufacturers and retailers try to avoid re-labelling after cold chain deviations – by contractually agreeing that the retailer prints the use-by date upon receipt of the goods – is not permitted under Article 6 of the FIC Regulation. This is because the manufacturer is obliged to ensure complete mandatory labelling before placing the product on the market; in other words, the product may not

be placed on the market without full mandatory labelling information. In summary, there are reasonable doubts as to whether this food operator–related scenario complies with the applicable food law. While the adjustment of a labelled date should not pose problems, provided it is accompanied by a clarifying note, leaving it open for the retailer to determine the date in the first place is not permissible. This conclusion is unsatisfactory. A more coherent approach would require mandatory information to be complete only upon reaching the consumer, rather than at the point of B2B placement on the market. Legislative clarification is warranted in this regard.

3 Future scenarios for official food control

Official food control authorities may also employ the digital twin in assessing unsuitability for human consumption, since food law requirements are, in principle, open to technological approaches—not only with respect to the methods chosen by food business operators, but also in the context of official food monitoring. As a result, the use of a digital twin and its repository data can reduce the administrative burden. In the event of an incident, the regulatory risk assessment can be carried out using the information provided by the digital twin.

3.1 Official use of non-accredited methods and their probative value

The use of new, i.e., previously unaccredited methods, some of which were used in the project, is regulated for official food monitoring with the help of the strict cascade of methods (cf. Art. 34 para. 1 Regulation (EU) No 2017/625 Official Controls Regulation). However, Art. 37 para. 5 lit. c) of the Official Controls Regulation facilitates innovation by allowing new methods to be used even before they have been assessed by the national accreditation bodies—provided that they have been validated by the laboratory using them.

The evidential value of innovative methods is also not necessarily lower than that of accredited methods. In administrative proceedings, the adjudicating court is bound by the procedural principle of the free evaluation of evidence (Sects. 98, 108 para. 1 sentence 1 of the German Code of Administrative Court Procedure (VwGO) in conjunction with Sect. 286 of the German Code of Civil Procedure (ZPO)). In the context of judicial evaluation of evidence, statements of the recognized methods might be considered to be more credible. However, this alone does not in principle exclude the evidential value of innovative, not yet accredited methods.

3.2 Exercise of discretion by the authorities with the help of the digital twin

The use of the digital twin can provide fact-based support for the exercise of discretion by the authorities; for example, in determining the appropriate enforcement measure in the event of a cold chain interruption. According to Section V, Chapter III No. 2 c) (i) of Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin, immediately after production a core temperature of 2 °C must be maintained during storage and transport. In the event of a cold chain interruption, the authority must take appropriate and necessary measures in accordance with Article 138 para. 1 and 2 of the Official Controls Regulation in conjunction with Sect. 39 para. 1 of the German Food and Feed Code (LFGB). In general, the authority has thus far consistently exercised its discretion in determining the legal consequences based on sensory, subjective impressions. With the help of the quantifiable probability data provided by the digital twin, this—in short—subjective impression would be replaced by a fact-based statement from the digital twin, thereby making the determination of legal consequences more objective.

3.3 Decision-making by the authorities using artificial intelligence

With effect from 1 January 2017, the legislature clarified in general administrative procedural law via Section 35a of the German Administrative Procedure Act (VwVfG) that the issuance of administrative acts by automatic devices is generally prohibited (see only Birner 2023). However, this provision is subsidiary to provisions in specific laws and does not cover administrative measures preparing for an administrative act (Lorse 2021).

The quantifiable probability statement of the digital twin is not an administrative act, rather it is, among other interpretations, a preparatory measure for the administrative act under Art. 138 of the Official Controls Regulation in conjunction with Sect. 39 of the German Food and Feed Code (LFGB) and it may already be used for this purpose. Only if the digital twin were able and to be empowered to issue an administrative act would a specific statutory provision be required—one that would take precedence over Section 35a of the German Administrative Procedure Act (VwVfG) in the field of official food control.

Another general open question concerns the transparency of decision-making processes in digital twins. If these processes are based on AI-supported risk assessments or predictive models, it must be ensured that their results meet the requirements of procedural fairness, legal certainty, and effective legal protection (Seitz 2024; Adelberger and

Franke 2025). Decisions must be comprehensible to those affected and to the courts. If the underlying models are opaque ("black box") due to their complexity or proprietary design, this can significantly impede judicial review. This is particularly true when digital twins not only provide supporting analyses but also effectively assume decision-making functions. In the present project, the quantifiable probability results generated by the digital twin are derived from traceable data sources and calculations, meaning that no "black box" exists here. Nevertheless, a cross-state guideline regarding minimum standards for transparency and explainability would be desirable for the use of AI to support administrative decisions.

4 Consumer-related future scenarios

4.1 Independent risk assessment by the consumer after the point of sale

The data stored and analysed in the digital twin—supplemented by the fridge temperature in the consumer's home, which may be entered manually—can also be used to determine whether the printed use-by date information remains valid. On this basis, a more precise assessment of the product's unsuitability for consumption by the consumer is possible, which can not only reduce the risk of foodborne health hazards, but also avoid unnecessary food waste (in general regarding legal aspects of food waste see Springer 2025).

4.2 Labelling requirements

In the B2C context, the question arises as to how information regarding a use-by date that differs from the one printed on the product can be communicated to the consumer via a digital device without being classified as misleading information. The option whereby the retailer updates the mandatory use-by date prior to the point of sale was already mentioned under 1.c). If the retailer also wishes to provide the consumer with additional voluntary information after the point of sale, for example, by updating the use-by date after purchase, this additional voluntary information must not be misleading either (Art. 36 (2) (a) of Regulation (EU) No. 1169/2011 (FIC)).

Based on the model of the reasonably well-informed average consumer who makes his decision attentively in a way that is appropriate to the situation, high demands must be placed on the respective content of the declaration so that the FBO cannot be accused of being misleading. In particular, care must be taken to ensure that the content is sufficiently distant from the use-by date already printed. Explanatory notes (e.g., 'Even after the use-by date has passed, the product can still be safely consumed for a further three days.') are more appropriate than other specific date details used in addition to the mandatory use-by date, in order to avoid any potential misleading information. In practice, every explanatory substantive reference must be checked for its misleading effect.

4.3 Civil liability towards consumers

If an incorrect calculation of the use-by date results in health impairments for consumers, the food manufacturer is liable under Sect. 1 para. 1 of the German Product Liability Act (ProdHaftG), which constitutes the implementation of European Product Liability Directive 2024/2853, as well as under tortious producer liability under Sect. 823 para. 1 of the German Civil Code (BGB). In the present context, the operator of the software used to determine the intelligent use-by date constitutes a further potentially liable party under the aforementioned provisions—a constellation that is facilitated in particular by the revision of the European Product Liability Directive 2024/2853, which now explicitly encompasses defective software. However, liability of the software operator towards the consumer under these provisions must ultimately be rejected on account of the producer's overriding final responsibility vis-à-vis the consumer (for an in-depth analysis of the civil liability relationships, see Korthals Altes 2026). Liability of the software operator would therefore require a legislative amendment; the producer's final responsibility towards the consumer appears sufficient as it stands. This does not, however, preclude the producer—in the event of liability towards the consumer—from seeking recourse against the software operator.

Overall, the producer therefore bears responsibility for ensuring the accuracy of the intelligently determined data; he must accordingly take measures to minimise the risk of erroneous outputs and ideally implement a system capable of detecting at least obvious miscalculations. On balance, it thus remains to be seen whether the advantages of the intelligent calculation method prove worthwhile in light of the necessary safety precautions when compared to conventional determination approaches.

5 Outlook

This analysis showed that the digital twin is a potentially effective tool for fulfilling the legal obligations of food business operators and official food control authorities. At the same time, it has become evident that certain areas of application involve either conflicting legal requirements or heightened demands for transparency and traceability, which necessitate a particularly cautious approach.

Food business operators are free to use tools such as a digital twin to intelligently determine shelf life, support their self-monitoring instruments, and assess whether food remains suitable for consumption following a cold chain disruption. The latter scenario may necessitate a change to the use-by date, which must be accompanied by clarifying information in order to ensure full regulatory compliance. For official food control authorities, the use of AI holds the potential, on the one hand, to reduce the workload involved in on-site inspections during routine checks (*Routinekontrollen*) by relying on data-based assessments. On the other hand, the use of the digital twin in cases of concern during ad hoc inspections (*Anlasskontrollen*) allows for the determination of specific immediate measures based on objective probability assessments. For consumers, the use of digital twins after the point of sale provides access to data-driven information that can also take temperature fluctuations into account, thereby contributing to the safe and, above all, sustainable handling of food after the point of sale. Regardless of whether a food business operator wishes to provide mandatory or voluntary information regarding the use-by date before or after the point of sale, they must always comply with the prohibition on misleading consumers.

From a legal perspective, the use of digital twins is therefore already permissible under the current legal framework (*de lege lata*) for both food business operators and official food control authorities. Looking ahead (*de lege ferenda*), harmonised national and European guidelines on the use of AI would nevertheless be desirable, particularly with regard to ensuring data quality and establishing clear requirements for the transparency and explainability of AI algorithms.

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Data availability The datasets generated and/or analysed during the current study are not publicly available due to legal restrictions but are available upon reasonable request.

Declarations

Ethical approval This article was conducted in accordance with established ethical guidelines. All participants provided informed consent prior to their participation. Data were collected and processed anonymously, and no personally identifiable information was stored. The study complied with institutional and national research ethics standards.

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

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