

Many Ways

AUGMENTING HUMAN MINDS: ARTIFICIAL INTELLIGENCE AND BIG DATA IN RISK ASSESSMENT

Summary

Risk assessment has reached its limits in the ability to be executed in a timely manner: recruiting relevant experts is increasingly demanding, while their physical capacity to identify, search, read, appraise, and integrate the exponentially growing amount of data in a structured way is stretched to a breaking point. Automation of the process and the application of artificial intelligence (AI) are anticipated to play an increasingly key role in future risk assessments. AI's potential contribution to the further advancement of risk assessment is two-fold: (1) identify and mine the available data and expertise that are relevant for a given risk assessment; and (2) execute parts of the risk assessment. This session will explore the role that AI can play in the conduct of future risk assessments and analysis of big data, what challenges its implementation may entail in a regulatory context, and how to transition to trustworthy AI systems for regulatory science.

Vision

AI and automation hold enormous potential to: (1) speed up the conduct of risk assessments; (2) keep up with the exponentially growing amount of data potentially relevant for risk assessments; and (3) manage and exploit big datasets. This would enable an "incremental" approach to future risk assessments; one that takes newly produced evidence into account and remains up to date in real-time. Consequently, to deliver more reactive risk assessments and ensure preparedness for future risk analysis needs, EFSA aims to implement AI approaches by 2027.

EFSA also envisages to adopt human centric AI techniques, as it is expected that humans and AI will operate together in complementarity for future risk assessments.

Background – Challenges and opportunities

In December 2018, the European Commission, together with EU Member States, developed a Coordinated Plan tailored to: (1) maximise the impact of both national and European investments in AI; and (2) foster synergies and cooperation on AI across the EU. The European Commission also appointed a group of experts (i.e., High-Level Expert Group on AI) to provide advice on its AI strategy.

In 2020, the European Parliament created a special committee on Artificial Intelligence in a Digital Age (AIDA) that seeks to develop a long-term strategy on AI

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and how AI can be used in the EU. Among other aspects, it investigates the impact of AI on the EU economy.

Overall, the use of AI technology is strongly recommended, as it may address global challenges such as climate change, transport, safety, and cybersecurity. Moreover, the volume of data and scientific evidence is growing exponentially, requiring complementary approaches for evidence identification, search, reading, appraisal, and integration.

The approach to AI currently explored and proposed at EU level is characterised by a highly human-centric AI component. This is because new tools and human-centric approaches, including AI, are required to take advantage of large datasets, including those considered for risk assessment purposes.

However, building trustworthy AI systems in support of future risk assessments will entail various challenges (such as robustness, generalisation, explainability, transparency, reproducibility, fairness, privacy preservation, alignment with human values, and accountability) that need to be overcome. Besides challenges, the use of AI and Big Data offers unique opportunities. It could speed up risk assessments, improve the quality of risk assessments (e.g., limit human error), enable discovering new patterns in the data landscape that are undetectable by humans, and keep risk assessments up to date despite the exponential increase of evidence.

Scope and objectives

The rapidly growing amount of available evidence to digest, the recruitment of relevant experts for the conduct of risk assessment, and their physical capacity to identify, search, read, appraise, and integrate large datasets in a structured way are increasingly challenging, requiring new tools and approaches. The use of AI holds great promise to overcome these challenges. Therefore, the thematic session will explore the role that AI can play in the conduct of future risk assessments and analysis of big data, what challenges its implementation may entail in a regulatory context, and how to transition to trustworthy AI systems for regulatory science.

The main objectives of the thematic session are to:

- Explore whether human expertise needed in risk assessment can be replaced partially or fully by AI-powered models.
- Discuss which parts of risk assessment processes are open to automation.
- Identify which risk assessment-related processes will continue to require human expertise.
- Explore whether future risk assessments will follow a “human-augmented” approach in which humans and AI operate together in complementarity.

- Make recommendations on how to develop trustworthy AI systems for regulatory science.

People behind the session

Session Coordinator: Angelo Cafaro (EFSA)

Chairpersons: Ilaria Del Seppia, European Medicines Agency (EMA); Guy Van Den Eede, European Commission

Moderators: Jennifer Baker, Freelance

Rapporteurs: Fulvio Barizzzone, European Food Safety Authority (EFSA); Angelo Cafaro, European Food Safety Authority (EFSA); Giulio Di Piazza, European Food Safety Authority (EFSA); Alejandro Platt Orzáez, European Medicines Agency (EMA)

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Many Ways – Session affiliate profiles

AUGMENTING HUMAN MINDS: ARTIFICIAL INTELLIGENCE AND BIG DATA IN RISK ASSESSMENT

Angelo Cafaro, European Food Safety Authority (EFSA)

Rapporteur

Angelo Cafaro is a data scientist at EFSA's MESE Unit where is involved in developing innovative methodologies for risk assessment based on AI and Big Data and providing supporting in the adoption of AI technologies. Prior to joining EFSA in 2020, he worked in the IT industry as project manager on complex multi-million, multi-partner, projects about AI and Big Data in the travel and banking domains. Previously, he worked as post-doctoral researcher at CNRS, in France, collaborating with research laboratories and institutions based in EU and US. He co-authored peer reviewed manuscripts published in international venues and worldwide recognized journals in the fields of AI and Human-Computer Interaction. He has been involved in the organization of international conferences and special tracks about AI, such as the socially interactive agents track at the 17th International Conference on Autonomous Agents and Multiagent Systems (AAMAS 2018 in Stockholm) and the Intelligent Virtual Agents series (from 2011 to 2017). He holds a PhD in computer science, from Reykjavik University in Iceland, focusing on AI, Natural Language Processing and Human-Computer interaction.

Raluca Crisan, Etiq AI

Speaker

Raluca has more than years of experience in data science working with a variety of clients (UK retailers, banks & telco companies). Raluca's experience spans managing teams to hands-on data product development. She is Co-founder & CTO of Etiq, an observability platform which supports the entire AI/ML lifecycle with Etiq Test, Monitor, Optimise and Explain. Prior to Etiq she was Director - Data Science for Merkle Aquila. She has also built the global analytics team for a mobile marketing company as it was being successfully listed on NASDAQ and has co-founded an ML start-up in the past. Raluca has a BA from Amherst College.

Title of talk: Watching the watchmen: testing AI systems intended for risk assessment

Abstract of talk

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In food safety and as part of building sustainable food systems, machine learning and AI can play a great role in operationalising risk assessment. The potential for efficiencies is high and machine learning and AI can make possible widespread implementations of food safety best practices that were not possible before. However, as in all other sectors where it is implemented, ML and AI can also pose their own risks which need to be addressed. From data collection, to data pre-processing, ML/AI application build, and through to production, potential issues can appear at every stage. It is hard to generalise the issue types across the range of potential applications. NLP, computer vision, supervised and unsupervised tabular data-based ML, reinforcement learning - they all have different potential risks and issues that need to be identified and mitigated. However methodology-specific trends emerge. For instance, in a system which incorporates end-user actions in online food safety risk assessments, such as in public consultations and crowdsourcing, the potential for data collection issues is high. Additionally, In some instances, the sample the system will score in a production setting can easily incorporate edge cases and distributions not reflected by the sample the system was initially trained on. Even if initially the samples were similar enough, over time as perhaps more users start using the system, the differences between the initial sample and more recent population can decrease the performance of the model. ML testing is coming through as a new discipline with its respective approaches to the different types of ML and AI methodologies. In this presentation we will cover strategies and approaches to identify and mitigate potential issues in ML and AI applications relevant to the food safety sector. We will cover a few different applications and then conclude with higher level recommendation and links to further resources to point the audience in the direction of further exploration.

Guy Van Den Eede, European Commission
Chair/Co-chair

Guy Van den Eede is an agricultural engineer (Catholic University Leuven, BE), specialised in plant molecular biology (State University Ghent, BE). He has been appointed at the Joint Research Centre of the European Commission in 1990 to provide technical support to the implementation of the EU policies on GMOs; later he has set up and managed the European Union Reference Laboratory for GMOs and the European Network of GMO Laboratories. In 2016, he was appointed Unit Head 'Knowledge for Health and Consumer Safety', covering life science-related files in the field of e.g. public health, food safety and security, toxicology, molecular biology and GMOs (with a particular focus on new plant breeding techniques). Special attention has been given to the impact of genomics on healthcare (prevention, diagnosis, treatment). Attention is given to anticipating knowledge needs and mapping knowledge gaps. Guy Van den Eede has been appointed (November 2019) acting Director for "Health, Consumers & Reference Materials" and for the management of

the Geel Site. Guy Van den Eede is a recognised expert in life sciences and has published over one hundred scientific papers.

Ilaria Del Seppia, European Medicines Agency (EMA)

Chair/Co-chair

Ilaria Del Seppia received her degree in Chemistry and Pharmacy from the University of Pisa (Italy) in 2003 and she is working at the European Medicines Agency (EMA) since 2005. In July 2020, she joined the EMA Veterinary Medicines Division as Data Scientist leading the development and implementation of the EMA Veterinary Data Strategy (2021 - 2027) and overseeing data aspects during the implementation of the Veterinary Medicines Regulation (EU Reg 2019/6). She represents EMA Vet Division in EU cross- Institutions and Agencies data initiatives (e.g. 1 substance 1 assessment) and coordinates the activities of the EU Veterinary Big Data Team with experts from EU Medicines Agencies developing and implementing the EU Veterinary Big Data strategy for the use of advanced analytics and emerging digital technologies in the veterinary regulatory domain. Previously, Ilaria served as project manager in the Pharmacovigilance and the Information Management division at EMA, leading the implementation of the first EU database on medicines for human use (XEVMPPD/Art.57 database) and its integration with key regulatory processes. At international level, within ICH and ISO forum she was the co-editor/co-lead of the international standards on identification of medicinal product (ISO IDMP) in synergy with international partners (FDA, Health Canada, Japan, WHO, EU medicines regulatory network) and contributed to its implementation in the EMA Master Data Management services (SPOR).

Akos Jozwiak, University of Veterinary Medicine Budapest

Panellist

Akos Jozwiak is the research director of the Digital Food Institute at the University of Veterinary Medicine, Budapest. Previously, he worked for the National Food Chain Safety Office (NÉBIH) and its predecessors for 15 years in various positions. In the recent years, he has worked in the area of strategic planning, food safety risk assessment and data analysis. He is a member of the European Food Safety Authority (EFSA) Advisory Forum and the EFSA Emerging Risk Exchange Network. He also chairs the EFSA Advisory Group on Data. In his research and education activities, he focuses on the area of development and application of new methods for improving the effectiveness of the controls of the food system. Within this domain, his main research areas are (1) applying computational science methods for identifying food system emerging risks; (2) applying data science for optimising food production; (3) determining the economic burden of food-borne diseases and

applying health technology assessment methods for food chain safety decision making.

Markus Lipp, Food and Agriculture Organization of the United Nations (FAO)

Panellist

Dr. Markus Lipp, senior food safety officer, is leading the food safety work in the Food Systems and Food Safety Division at the Food and Agricultural Organization of the United Nations (FAO) and coordinating FAO's work on providing chemical and microbiological food safety risk assessment and capacity development work to strengthen national capacities for food safety. Dr. Lipp previously worked as the Senior Director for Food Standards at the U.S. Pharmacopeia (USP) where he was responsible for the Food Chemicals Codex (FCC). Prior to this position, he worked as Director for Science and Research at the International Bottled Water Association and as the Global Lead for Detection Methods and Reference Materials relevant to genetically modified organisms at Monsanto Co's headquarters in St. Louis, MO. Furthermore, his experiences include working for Unilever at its Dutch research facility and for the Joint Research Center (JRC) of the European Commission at its facility in Italy, both position focused on ensuring food authenticity and safety, including the presence of genetically modified organisms in food. Dr. Lipp holds a Ph.D. in analytical chemistry from the University of Karlsruhe, Germany.

Rens Van de Schoot, Utrecht University

Panellist

Prof. Dr. Rens van de Schoot works as full professor 'Statistics for Small Data Sets' at Utrecht University in the Netherlands. He is also program director of the research master 'Methodology and Statistics for the Behavioural, Biomedical and Social Sciences' and coordinator of the post-graduate program at the Department of Methods and Statistics. His main research projects are the open-source ASReview project (Active learning for systematic text reviewing) and solutions for small data sets (S4) in the field of structural equation modeling with solutions in the areas of expert elicitation, Bayesian statistics and constrained statistical inference. He was elected to become a member of the Young Academy of the Royal Netherlands Academy of Arts and Sciences (KNAW) and of the Society of Multivariate Experimental Psychology (SMEP). He obtained a VENI (on Integrating background knowledge about traumatic stress experienced after trauma into statistical models assessing individual change over time) and a VIDI (on Experts, their prior knowledge, and the issue of limited data). The ASReview project was awarded the KNVI- Victorine van Schaickfonds Initiative Award.

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Hans Marvin, Wageningen Food Safety Research (WFSR)

Speaker

Dr. Hans Marvin studied chemistry at Free University of Amsterdam (VU) and received his MSc in 1985. Afterwards, he studied Biotechnology at University of Groningen and received his PhD in 1988. Following a few Post-doc positions, he started as senior scientist (biochemistry) at Centre for Plant Breeding and Reproduction Research (CPRO) in Wageningen, the Netherlands in 1991, leading the section Quality Improvement. In 1999, he moved to RIKILT Wageningen UR, now called Wageningen Food Safety Research (WFSR). At present, Dr. Hans Marvin is a senior scientist specialized in many aspects of food safety, including analysis of foods, research on safety, and risk assessment for authorities. He works on a number of food safety issues, including emerging risk, big data and Artificial Intelligence (AI), food/ feed issues related to biotechnology and nanotechnology and risk analysis and has initiated various activities within the Netherlands and EU in these fields. Dr Marvin's personal research specialisms are (i) methods for early warning & emerging risk identification, (ii) application of a system approach to food safety and modelling, (iii) application of Bayesian Networks in prediction models for food safety and food fraud, iv) introduction of big data analytics in food safety research including big data infrastructure. On these topics he has organized and chaired numerous workshops and is author and co-author of over 100 peer-reviewed scientific publications.

Title of talk: Opportunities of Big Data and AI in Food Safety Risk Assessment

Abstract of talk

The EU Farm-to-Fork strategy refers to One Health as an approach for tackling emerging issues, and underlines the need for holistic transdisciplinary approaches to move towards safe and sustainable food systems. Sustainable food systems are embedded in a complex web of interacting drivers from within and outside those systems, influencing food supply chain performance both locally and globally. These drivers include: (i) a growing world population and changing diets; (ii) climate change; (iii) diminishing biodiversity; (iv) governance; (v) (competing) agricultural systems; (vi) market structure, economic development & financial structures; (vii) urbanisation; (viii) policies; (ix) technology & innovation; (x) consumer behaviours, etc. Understanding the complexity of the food supply chain, including the drivers and their interrelationships, is key in developing methodologies to transform the EU food system ('from Farm-to-Fork', producing a more sustainable, safe and healthy diet). A systems-based approach that takes this web of indicators into account is therefore required, supported by digital innovations (artificial intelligence and big data technologies). This presentation will show examples of the implementation of systems-based approaches, with the development of prediction models for food

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safety and food fraud, in which expert consultations and AI play a key role. In particular, the use of Bayesian Networks has shown promising results. Examples of the application of AI algorithms to media text and scientific literature will also be given; the focus is on collecting, processing and visualising data as an intelligence activity to improve food safety control. Lastly, examples will be given of novel technologies developed to screen food samples online, or used onsite for food safety risks, using big data and AI. It is concluded that big data in food safety is not yet being fully applied and that big data infrastructures and acceptable data governance methodologies (security, ownership etc.) are needed.

Giulio Di Piazza, European Food Safety Authority (EFSA)

Rapporteur

Giulio Di Piazza is a Data Scientist at the EFSA' Methodology and Scientific Support (MESE) Unit. He has a solid background in mathematics and statistics. His work is mainly related on the support of Scientific Officers with statistical analysis and methodologies for food risk assessment, and support with data modelling and data manipulation. Before, he was working as Data Manager in the EFSA Evidence Management Unit (DATA), where he was in charge of building and maintaining data flows for any monitoring data collections for food and feed samples, throughout the entire data life cycle; plus, he was acting as SAS expert giving support in the maintenance of the system and servers, and technical support to data managers and scientific officers; lastly, he was managing data projects and external contractors. Before joining EFSA he worked as Business Intelligence specialist. Giulio studied Mathematics focusing on Algebraic Geometry and its application to Cryptography. He holds a double master's degree from the university of Padua and the university of Bordeaux I, and a university school of excellence diploma from the Galilean School of Higher Education of Padua.

Fulvio Barizzone, European Food Safety Authority (EFSA)

Rapporteur

Fulvio Barizzone is Senior Scientific Officer at the EFSA' Methodology and Scientific Support (MESE) unit. Fulvio is a veterinarian by training and has more than 20 years of professional experience. Since 2014 his area of work is mainly related to literature reviews (systematic reviews or parts of them, scoping and narrative reviews) and protocol development for EFSA assessments. In this context his main interests are related to the automation of the systematic review process through data interoperability and the use of artificial intelligence. Before working in this area Fulvio was working on epidemiology of animal Transmissible Spongiform Encephalopathies (TSEs) at the Italian reference centre for animal TSEs, on veterinary pharmacovigilance at the Italian ministry of health and on epidemic

surveillance of animal diseases at the Istituto Zooprofilattico Sperimentale dell'Umbria e delle Marche. Fulvio joined EFSA in 2005 where until 2013 he was assisting in coordinating the workflow of the TSEs and animal by-products related mandates of the Biological Hazards unit. Fulvio holds two postgraduate specialization degrees (animal health and veterinary legislation) and a Master's degree in biostatistics and epidemiology.

Alejandro Platt Orzáez, European Medicines Agency (EMA)

Rapporteur

Alejandro Platt Orzáez received his degree in Veterinary Medicine from the University of Córdoba (Spain) in 2020. Alejandro joined the European Medicines Agency (EMA) as part of its traineeship programme in October 2020 within the Evaluation and Innovation Department of the EMA Veterinary Medicines Division. In this role he had the opportunity to work closely with the Head of EMA Veterinary Biologicals and Emerging Therapies Service contributing to a range of key regulatory tasks such as defining the rules related to veterinary limited markets in liaison and cooperation with the European Commission for the revision of the legal framework for veterinary medicines. In September 2021, Alejandro joined the EMA Veterinary Strategic Support Office as change management support for the Veterinary Regulation 2019/06 programme contributing to the effective roll-out of the programme change management plan. In this role, Alejandro supports the development of training materials, delivery of training and coaching sessions with Member States, contribution to communication and awareness-raising activities to the programme stakeholders such as healthcare professional providers, veterinary pharmaceutical Industry and regulatory partners. Alejandro has recently joined the Union Product Database (UPD) Analytic Team at the EMA to contribute to the definition of data analytics methodology to leverage dissemination and integration of Veterinary Medicines information and contribute to the activities.

Jennifer Baker, Freelance

Moderator

Better known as Brusselsgeek, Jennifer has been a journalist in print, radio and television for 20 years, the last 10 years specialising in EU policy. Regularly listed as one of the top influencers in the EU bubble, Jennifer was awarded #1 Tech Influencer 2019 by ZN, was listed by Politico as one of the Top 20 Women Shaping Brussels in 2017, and was named by Analytica as one of the world's Top 100 Influencers on Data Security 2016. She regularly features as an EU expert on BBC radio, Euronews, SkyNews and others, and hosts Brussels' must-watch weekly roundup show TOTW for Euractiv. From editing a national daily paper in Malta, to reporting on European affairs for Middle Eastern television, she has worked across a

wide range of media, and has a wealth of experience in navigating the political quagmire of the EU. Jennifer is skilled at translating EU policy-speak into understandable English. She has written for some of the biggest names in media, including ArsTechnica, NBC, TheNextWeb, The Register and The Times. For more information please see: www.brusselsgeek.com

Ivana Bartoletti, Wipro Panellist

Ivana Bartoletti is the Global Data Privacy Officer at Wipro, the leading international information technology, consulting and business process services company. Ivana is an internationally recognised thought leader in the fields of privacy, data protection and responsible technology. She has many years of experience working for large organizations in privacy policy, strategy and programmes related to digital transformation, cloud and automation. The Cyber Security Awards named her Woman of the Year (2019).

As a Visiting Policy Fellow at the University of Oxford, her research focuses on how to advance the global sharing of information in the context of privacy, security, data protection and human rights.

Ivana is co-editor of The AI Book, a handbook for investors, entrepreneurs and fintech visionaries and is author of An Artificial Revolution, on Power, Politics and AI. She is founder of the influential Women Leading in AI network. A sought-after subject expert, Ivana is interviewed frequently in the mainstream media and speaks at many international events.

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