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Regulatory aspects of risks posed by veterinary medicinal products to European necrophagous birds: A case study with nonsteroidal anti-inflammatory drugs (NSAIDs)☆

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ABSTRACT

Nonsteroidal anti-inflammatory drugs (NSAIDs) are used in human and veterinary medicine to treat pain and inflammatory diseases. However, the uncontrolled treatment of free-roaming and sheltered livestock with NSAIDs, mainly diclofenac, has caused catastrophic impacts on the biodiversity of necrophagous birds. For instance, a decline of up to 95 % in populations of various species of vultures occurred in South Asia from the late 1990 s to the early 2000 s. In the European context, the European Commission mandated the European Medicines Agency (EMA) to assess the risk posed by diclofenac to necrophagous bird populations in 2014. The risk assessment conducted by the EMA in 2014 identified the risks to affected species. Specific risk-management measures were proposed to facilitate an acceptable level of protection for necrophagous bird populations. Over the last ten years, just one evident death of a necrophagous bird due to intoxication with diclofenac was recorded in Europe. However, the concentrations of different NSAID residues detected in bird carcasses and tissues indicate exposure of avifauna to this group of pharmaceuticals, suggesting that scavenging birds in Europe are not protected against NSAIDs and other veterinary medicines used in animals for human consumption. In addition, NSAIDs are widely used in human medicine and are commonly detected in surface waters of EU member states. We assessed the risk of secondary poisoning based on the detected concentrations of diclofenac in surface waters and identified a risk for piscivorous raptors. We conclude that obligatory risk assessment followed by risk-management measures during the authorisation process does not sufficiently reduce the risk of pharmaceuticals for necrophagous and piscivorous raptors. We propose recommendations and alternative risk-management strategies, underscoring the urgency of protecting European necrophagous and piscivorous raptor populations to sustain the crucial ecosystem services they provide.

1. Introduction

Chemical pollution is among the leading threats to wildlife globally (IUCN, 2024). In this regard, it has recently been convincingly argued that chemical pollutants are likely underestimated drivers of biodiversity loss (Groh et al., 2022; Mueller et al., 2023). Chemical pollution represents a plausible mechanistic contributor to the biodiversity declines reported across insects (Scherber et al., 2026), amphibians

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(Luedtke et al., 2023), plants (Jandt et al., 2022), mammals (Brodie et al., 2006), and birds (Burns et al., 2021; Ogada et al., 2022). One important class of such pollutants is active pharmaceutical ingredients (APIs), which can disrupt a wide range of fundamental processes in wildlife, including development, reproduction, physiology, morphology and behaviour (Bean et al., 2024; Bertram et al., 2022; Brand et al., 2025; de Solla et al., 2023; Zimmer, 2025). One particularly concerning class of API pollutants is the nonsteroidal anti-inflammatory drugs (NSAIDs), a class of medications that reduce inflammation, pain, and fever, primarily by inhibiting cyclooxygenase (COX) enzymes involved in prostaglandin synthesis (Izadi et al., 2020). Indeed, the most well-known and severe impact of APIs in the environment reported to date was driven by NSAID contamination: the Asian vulture crisis.

Starting in the early 1990 s, populations of three *Gyps* vulture species in South Asia—the white-rumped vulture (*Gyps bengalensis*), slender-billed vulture (*Gyps tenuirostris*), and Indian vulture (*Gyps indicus*)—plummeted by over 95 % (Prakash et al., 2003; Oaks et al., 2004). This represented a collapse from historic populations of approximately 40 million individuals to only around 19,000 birds by 2017 (Prakash et al., 2019; MoEFCC, 2020). The primary cause of this collapse was the widespread veterinary use of the NSAID diclofenac, with vultures feeding on contaminated livestock carcasses and consequently suffering severe visceral gout (Oaks et al., 2004). As a result, the veterinary use of diclofenac was banned in India, Pakistan, and Nepal in 2006, and in Bangladesh in 2010 (Chaudhry et al., 2012; Prakash et al., 2012; Khan, 2013; Cuthbert et al., 2016). Then, in 2012, India, Pakistan, Nepal, and Bangladesh reached an agreement to formalise these actions and their implementation through an intergovernmental Regional Declaration (Governments of Bangladesh, India, Nepal, and Pakistan, 2012). The effectiveness of these bans, and subsequent regulatory efforts, has varied over time and across the affected countries. Encouragingly, a significant reduction in the availability of diclofenac in Nepal has resulted in a notable recovery of vulture populations since 2012 (Galligan et al., 2019).

The decline of vulture populations in Asia due to poisoning by diclofenac has increased awareness of the potential consequences of exposure of raptors and vultures also in Europe (Cook et al., 2024; Margalida and Green, 2025), which hosts four resident vulture species (Eurasian griffon *Gyps fulvus*, cinereous *Aegypius monachus*, bearded *Gypaetus barbatus*, and Egyptian *Neophron percnopterus*). International policy responses have also sought to address this threat. Resolution 11.15 (Rev.COP15) of the Convention on the Conservation of Migratory Species of Wild Animals (CMS) urges Parties and relevant Range States to strengthen the regulation of veterinary NSAIDs through safety testing, withdrawal of licences for vulture-toxic NSAIDs such as diclofenac or comprehensive risk assessment, and the identification and promotion of safe alternatives (UNEP/CMS, 2026).

In the EU a new veterinary medicinal product (VMP) cannot enter the market without the approval of a competent authority. Prior to 1995, a VMP could only be authorised at a national level (Fabrega and Carapeto, 2020). Since Council Regulation (EEC) No 2309/93 came into force in 1995, a VMP can be authorised in three ways:

- Centralized authorization, which is granted by the EU Commission based on a scientific evaluation by the European Medicines Agency (EMA) in all member states.
- Decentralized authorization, which is managed by a national authority and agreed upon by other national authorities (several countries or one individual country agrees on approval).
- National authorization, which occurs in one member state only, and is very rare.

Member state(s) can also trigger a product or class referral when new evidence indicates that safety (including safety for the environment) requires a re-evaluation of the centralised authorisation of a product or active substance class.

Regulation (EEC) No 2309/93 also introduced product-based ERA for all new applications, regardless of the centralised or national procedure, and it should follow guidelines VICH GL6 (VICH, 2000), VICH GL38 (VICH, 2004), and supporting guidelines. The protection goals are set at the ecosystem level, protecting its structure and function, including specific communities, for example dung fauna. However, not all functional ecosystem niche groups are considered in the guidelines—e.g., necrophagous birds are not specifically mentioned. Nevertheless, when there are indications that environmental risk could arise beyond the scope of the protection goals, the provision under the "however clause" can be applied, and risk should be assessed for species, communities, or ecosystems that may be at risk. The environmental risk is estimated by comparing predicted environmental concentrations (PEC) to predicted no-effect concentrations (PNEC). The latter are derived from the highest concentrations that do not produce an adverse apical physiological effect in model-tested species. This concentration is divided by a standard safety factor. As part of ERA, the assessment of secondary poisoning focuses on the potential for bioaccumulation through the food chain and compares predicted concentrations in the diet of top predators with no-effect levels derived from laboratory studies. When a risk to the environment cannot be excluded, the applicant may propose risk-management measures that should mitigate the risk. The result of the ERA of VMPs is part of the benefit/risk analysis. When the VMP presents a risk to the environment, and no risk-management measures can mitigate this risk, the benefit/risk balance may be negative, resulting in a refusal of marketing authorisation (EMA, 2024).

Diclofenac has been authorised for veterinary use in five European countries (Spain, Italy, Latvia, Estonia, and the Czech Republic) for decades (Herrero-Villar et al., 2024) without any post-authorization commitments and risk-mitigation measures. The main use of diclofenac, however, is human medicine, where it is widely used to treat pain associated with arthritis, dysmenorrhea, rheumatic diseases, and various inflammatory disorders, as well as kidney stones, gallstones, and acute migraines (Moreno-Opo et al., 2021). Diclofenac is listed on the updated list of water pollutants, which includes newly identified substances that damage the environment and human health (EC, 2026).

This article summarises an opinion "On the risk to vultures and other necrophagous bird populations in the European Union in connection with the use of veterinary medicinal products containing the substance diclofenac" based on the *ad hoc* ERA prepared by the European Medicines Agency in 2014 (Kolar et al., 2014). The methodology used acknowledges the ecology and behaviour of targeted species. The *ad hoc* risk assessment methodology could be used as a standard approach for the risk assessment for veterinary and human pharmaceuticals. Beyond reviewing the well-established toxicity of diclofenac to vultures, the central contribution of this article is to examine whether the established European regulatory risk assessment framework for pharmaceuticals adequately translates an identified environmental risk into effective protection, using approximately ten years of post-assessment evidence as a case study. To this end, we evaluated the efficiency of risk-mitigation measures that should protect necrophagous birds in Spain, which were set based on EMA risk-management recommendations, against measured NSAID residues in domestic animal carcasses and in necrophagous birds and documented intoxication cases. In addition, using the maximum acceptable concentration of diclofenac from the CVMP opinion, and based on monitoring data from surface waters, we estimated the risk of secondary poisoning for raptors feeding on diclofenac-contaminated fish. This modelled risk, which extrapolates *Gyps* vulture toxicity data to piscivorous raptors, demonstrates that current ERA does not consider this specific exposure route. We provide a review and policy analysis that synthesises the outcomes of environmental risk assessments, the potential for secondary poisoning, and existing management measures. Finally, we discuss which alternatives and risk-management measures are both scientifically sound and socio-economically feasible to reduce chemical stress on vulture populations

and thereby associated effects on their ecosystem functions, to ultimately help protect biodiversity from chemical pollution.

2. Summary of the *ad hoc* risk assessment for diclofenac to necrophagous birds with risk-management measures

2.1. Scope and protection goals

Under pressure from the public and NGOs, the EU Commission asked the European Medicines Agency (EMA) to provide a scientific opinion on whether there is a risk from the use of VMPs containing diclofenac to vulture populations and other necrophagous birds in 2014 (EMA, 2014). The responsible body of EMA, the Committee for Veterinary Medicinal Products (CVMP), was asked to give its opinion regarding:

(i) The risk that the use of veterinary medicinal products authorised in the EU containing the substance diclofenac may represent to vultures and to other necrophagous birds in the EU, taking into account the EU rules on animal by-products.
(ii) If a risk is identified, any actions or mitigation measures that could be implemented to manage the risk effectively.

The CVMP opinion includes *ad hoc* ERA (Kolar et al., 2014) and takes into account the responsible use of VMPs containing diclofenac in cattle, pigs, and horses and the established withdrawal periods in cattle and pigs. It also includes other realistic exposure scenarios for necrophagous birds feeding on carcasses containing diclofenac residues in feeding stations or fallen stock in pastures. Evaluation of the risk to vultures and other necrophagous birds from ingestion of carcasses of animals treated with diclofenac-containing VMPs is not covered by existing environmental risk assessment guidelines VICH GL6 (VICH, 2000), VICH GL38 (VICH, 2004), and supporting CVMP guideline (EMA, 2016). Lacking suitable default parameters and established ERA methods, an *ad hoc* approach was adopted, using expert judgement to identify an appropriate model species and inter- and intra-specific extrapolation factors. Evaluation of exposure included behaviour patterns and ecological strategies of necrophagous birds.

2.2. Identification of bird species at risk

Populations of birds that display a necrophagous feeding behaviour in the EU have been considered species of concern. The metapopulations of necrophagous birds that might be potentially affected by diclofenac in Europe from the *Accipitridae* family are listed in Table 1.

Both species of eagles and kites do not solely rely on carrion. Nevertheless, toxicity of diclofenac could contribute to a decline of their populations. Other birds that occasionally appear on the feeding stations (common buzzard, raven, species of gulls) were excluded from the ERA because mammalian carrion is not their primary food source, and thus they are not considered to be at risk.

The VICH GL38 (VICH, 2004) Phase II environmental risk assessment guideline states that the protection goal of the environmental risk assessment "is to assess the potential for VMPs to affect non-target species and communities from terrestrial and aquatic environmental compartments". However, this broad definition was insufficient for necrophagous birds, as most at-risk species were in 2014 on the IUCN Red List (https://www.iucnredlist.org). Given the varying European threat status-rare for cinereous vultures and golden eagles, endangered for Egyptian vultures and Spanish imperial eagles, vulnerable for bearded vultures and black kites, and declining for red kites)-the assessment's protection level has been set at the probability of the death of a single individual.

Table 1
Necrophagous bird species considered in the 2014 CVMP ad hoc assessment of the risk posed by veterinary diclofenac to vultures and other necrophagous birds in the EU (EMA, 2014).

Taxonomic group	Species
Vultures	Griffon vulture (*Gyps fulvus*)Cinereous or black vulture (*Aegypius monachus*)Egyptian vulture (*Neophron percnopterus*)Bearded vulture (*Gypaetus barbatus*)
Eagles	Golden eagle (*Aquila chrysaetos*)Spanish imperial eagle (*Aquila adalberti*)
Kites	Red kite (*Milvus milvus*)Black kite (*Milvus migrans*)

Populations of vultures and eagles fluctuate close to the maximum population size sustained in a particular environment, as these species typically follow the K-selection reproductive strategy (Santangeli et al., 2018). Adaptations to stable environmental conditions result in relatively stable populations. Vultures, for example, produce low numbers of offspring, gestation and incubation are protracted and are followed by slow maturation and extended parental care (Santangeli et al., 2018). The lifespan of some vulture species is up to 50 years (del Hoyo et al., 1994). The slow reproduction rate of endangered K-selected species makes them particularly vulnerable and conservation plans for these species need careful planning and are often costly. The EU invested €11 million in vulture conservation projects in the period from 2008 to 2012 (source: BirdLife International in EMA, 2014). For instance, the estimated cost to breed a bearded vulture in captivity for reintroduction into the wild has been established at €70–80,000 (Frey, 1998).

The CVMP acknowledged a peer-reviewed modelling study which indicated that less than 1 % of contaminated carcasses were needed in India to trigger the collapse of vulture populations, assuming birds fed only on livestock carcasses (Green et al., 2007). The high incidence of intoxication is due to foraging behaviour and feeding frenzies of bird parties that scan the area for food. Birds descending to the carcass typically attract all other vultures within visible distance, which can extend up to 15 km. Consequently, in a matter of minutes, a few dozen vultures of different species can gather and feed on the carcass. Intoxication through feed in such cases can kill large numbers of birds and pose a critical threat to smaller vulture populations (Xirouchakis and Andreou, 2009; Monsarrat et al., 2013; Curk et al., 2025).

2.3. Exposure assessment: potential exposure routes for necrophagous birds

Exposure assessment should determine the likelihood of necrophagous birds feeding on carcasses of treated animals and estimate diclofenac levels in these contaminated carcasses. Residue studies were provided in the MRL Summary Report on diclofenac by the marketing authorisation holder using the commercial product at the maximum dose (2.3 mg/kg fresh tissue) and duration (3 d) in pigs and cattle (EMA, 2003). As a worst-case scenario, a 3-d period between treatment and exposure to birds was chosen as it is very unlikely that animals will be treated with diclofenac immediately before they die (EMA, 2003). The reasonable worst-case amount of diclofenac in the injection sites available for consumption by birds would be approximately 37 mg in cattle and 0.9 mg in pigs (EMA, 2003). Ten days after the treatment, the residue concentrations in all cattle tissues were below 3 μg/kg, and 9 d after the treatment of pigs the residue concentrations in tissues were no longer detectable (EMA, 2003).

In the EU, the following two main potential routes of exposure of necrophagous birds to diclofenac used in VMPs have been reported by stakeholders from replies to the public consultation:

(i) Exposure at feeding stations—from animal by-products from slaughterhouses—from animals that have died from natural causes taken to feeding stations by farmers.
(ii) Exposure through fallen stock animals that die in open pastures from natural causes and are left in fields to be disposed of by vultures and other wild animals.

2.4. Toxicity of diclofenac to necrophagous birds

The mechanism of toxicity of diclofenac to raptors has been studied in the white-backed vulture (*Gyps africanus*), revealing that damage of renal tubular epithelial cells leads to the accumulation of uric acid in plasma, which eventually causes kidney failure (Naidoo and Swan, 2009). Diclofenac intoxication in vultures manifests clinical signs such as lethargy, ruffled feathers, closed eyes, and a neck drooping (Swan et al. 2006). Within 12 h, kidney failure leads to a catatonic state and severe dehydration (Swan et al., 2006; Hussain et al., 2008). Diclofenac causes necrosis, reduced uric acid excretion, renal failure, visceral gout, and death within days of exposure (Oaks et al., 2004).

Severe impacts on various *Gyps* populations in South Asia (Prakash et al., 2003; Oaks et al., 2004), together with experimental data on the African white-backed vulture (*Gyps africanus*) and the Eurasian griffon vulture (*Gyps fulvus*), confirm that *Gyps* species are susceptible to diclofenac (Swan et al., 2006). Based on these findings, Swan et al. (2006) suggested that diclofenac is likely toxic to all eight *Gyps* species.

The differences in sensitivity between species might be related to differences in the metabolic half-life of the drug across species. The lethality of diclofenac to the Oriental white-rumped vulture (*Gyps bengalensis*; Green et al., 2007) is 22–50 times lower than the lethal dose in poultry (Reddy et al., 2006). Diclofenac toxicity has also been demonstrated in a non-vulture species of the Accipitridae family, the steppe eagle (*Aquila nipalensis*), based on post-mortem lesions and diclofenac residues in birds found dead at a cattle carcass dump (Sharma et al., 2014). For the Egyptian vulture (*Neophron percnopterus*) and the red-headed vulture (*Sarcogyps calvus*), susceptibility to diclofenac is inferred from population declines on the Indian subcontinent that slowed after the 2006 ban on veterinary diclofenac (Galligan et al., 2014). Thus, it is important to consider that, although data are missing for other species, those in the same family might also be at risk—for instance, the golden eagle (*Aquila chrysaetos*). On the contrary, other vulture species appear to be relatively insensitive, such as New World vultures (Rattner, 2009).

The Oriental white-rumped vulture (*Gyps bengalensis*) has been chosen as the model organism for risk assessment since this was the only species for which laboratory and field toxicity data on diclofenac were available (Swan et al., 2006). In the study, the results of the estimation of diclofenac's effect on the Oriental white-rumped vulture were extrapolated to other species at risk in the European Union.

The study that demonstrated the high toxicity of diclofenac to *Gyps* species indicated that the white-backed vulture *G. africanus* and Eurasian griffon vulture *G. fulvus* are likely to be at least as sensitive to diclofenac poisoning as *G. bengalensis*, which has an estimated LD_{50} of 0.225 mg/kg bw/d (Swan et al., 2006). This is the only available lethal dose derived from the dose–response relationship based on the acute oral toxicity study in Oriental white-rumped vultures in which the mortality was measured at different dose levels (Swan et al., 2006). With a meat consumption of 1.023 kg per meal (Green et al., 2007), the corresponding diclofenac lethal concentration in feed (LC_{50}) is 1.044 mg/kg feed. Using the LD_{10} of 0.074 mg/kg bw/d calculated from the same study by Green et al. (2007), the derived LC_{10} was 0.343 mg/kg feed.

Based on the protection goal determined for this assessment—i.e. the protection of individuals and not at population/community level—to ensure the safety of all potentially exposed scavengers, an assessment factor of 100 (10 to account for species-to-species variability × 10 to account for variability in species life stages) on the lowest LC_{10} was applied.

2.5. Risk characterisation: combining exposure and toxicity data to estimate the risk to bird populations

To ensure the safety of necrophagous birds, the maximum acceptable concentration of diclofenac residues in tissue should not exceed 3 μg/kg (LC_{10} 0.343 mg/kg feed/100). Considering tissue concentration of diclofenac residues, the following scenarios were established to assess the risk:

Use of slaughterhouse material in feeding stations: Vultures feeding at stations using slaughterhouse by-products from cattle and pigs pose no risk when 15-d and 12-d withdrawal periods, respectively, are observed. The scenario also assumes that the by-products are primarily organs, not injection sites.

Exposure through dead treated animals in intensive production: The risk of exposure to diclofenac for necrophagous birds is considered high when animals treated with the drug die shortly after treatment in intensive farming situations, before diclofenac levels are reduced to the safe concentration of 3 μg/kg.

Exposure through fallen stock in extensive production: extensive livestock producers leave dead animals in the field due to weak control over the stock, or intentionally, to be consumed by scavengers. Risk cannot be excluded when animals are treated with diclofenac before release on the pasture, and then they die in the field. The probability of exposure of vultures is high given that birds typically notice the carcass within 30 min.

2.6. Risk-management measures that followed the identified risk

The CVMP suggested the following risk-management measures to supplement those already in place in EU member states described in Table 2.

3. NSAIDs in surface waters: Risk of secondary poisoning for piscivorous birds

Necrophagous birds normally do not prey on fish and only occasionally feed on dead fish and other aquatic organisms. NSAIDs that may bioaccumulate in fish are not the main exposure route for these birds. However, the concentration especially of diclofenac and other NSAIDs emitted from human use to EU surface water may be of concern for fish-eating raptors. The primary piscivorous raptors of concern in Europe are osprey and white-tailed eagle since they feed either solely or partly on fish (del Hoyo et al., 1994; Nadjafzadeh et al., 2016). Thus, chemical monitoring data on concentrations of NSAIDs in surface waters could be used to assess the exposure status and risks of secondary poisoning with NSAIDs via the aquatic food chain in piscivorous raptors.

The Joint Research Centre systematically reviewed concentration data from field monitoring for diclofenac and ibuprofen (JRC, 2022, 2023). Measured diclofenac concentrations in EU surface waters, totaling more than 48,000 samples from 3,438 sampling sites in 26 Member States, showed a 95th percentile concentration of 0.28 μg/L. This is seven times higher than the AA-EQS for freshwater of 0.04 μg/L. Further, ibuprofen was measured in more than 43,000 samples from 3,622 sampling sites in 15 Member States but was found in lower concentrations (a 95th percentile concentration of 0.107 μg/L; JRC, 2023). In contrast, no systematic and standardised EU-wide monitoring data are available for other NSAIDs. Thus, to give a broad estimate of the most recent occurrence and concentration ranges in European surface waters (rivers, lakes, streams, marine waters) and to highlight the related potential exposure risk for fish-eating raptors and birds via the aquatic food chain with NSAIDs from human use, we extracted data on NSAID concentrations from the NORMAN database. Specifically, we searched for reported concentration ranges of 15 NSAIDs between 2010 and 2020 in EMPODAT (https://www.norman-network.com/nds/empodat/). NORMAN receives data from national monitoring programmes, research institutions, and regulatory agencies, using standardised templates to ensure data quality and comparability. However, an exhaustive literature review or in-depth analysis of the NORMAN data was out of scope of the current work.

We used R (v. 4.5.1; R Core Team, 2019) to create heat maps showing the average concentration derived from NORMAN levels of NSAIDs in

Table 2
Recommendations issued by the Committee for Veterinary Medicinal Products (CVMP) following the *ad hoc* risk assessment on risk-management measures and their expected effects on the reduction of risks posed by diclofenac to necrophagous birds in Europe.

Measure	Recommendation	Expected mitigation effect
Information to veterinarians	The product might only be supplied with a veterinary prescription; veterinarians and animal owners should be knowledgeable about the risks of the product to necrophagous birds to ensure compliance.	No exposure of vultures to carcasses from treated animals containing diclofenac residues.
Warnings in the product literature:	The SPC* and package leaflets, which are addressed to the veterinarian and animal holder (farmer), respectively, should contain highlighted warnings indicating the desired protection and restriction of use. Contraindications for extensive pasture animals could be considered. Horses not intended for human consumption are likely to end up in a feeding station, and this should be reflected.	Since, at the time of the preparation of the report, all authorisations were carried out by the national procedure, the national authorities are responsible for implementing this measure.
Change in the administration pattern of the veterinary medicinal product	Administration of the product by the veterinarian to prevent animals at risk of being consumed by vultures.	Daily veterinarian visits to the animal for 3–5 d. Alternatively, only the exact dosage for the treatment could be kept in the farm for its administration by the farmer under veterinary supervision.It is recognised that once the animal is medicated, the fate of the carcass is not under the control of the veterinarian.
Changes in the food chain information (FCI)	Food chain information should contain additional information specifying if the animal has been treated with diclofenac during its life. The content of the FCI, detailed in EU legislation, should be amended.	Slaughterhouse operators should be informed that if the withdrawal period of the animal has not been respected, the animal cannot be taken to a feeding station.
Increase controls in farms intentionally leaving dead animals in the field	The farmers can be allowed to leave fallen stock on fields. To do this, farmers must meet certain requirements and must be authorised by the competent authorities.	It would be an appropriate measure to increase the frequency of controls in these farms and the checks of the farm book looking for the use of diclofenac. Contraindications for extensive pasture animals could be considered.
Accompanying document for by-products	A new document can be developed to be prepared by the farmer or slaughterhouse operator.	The document would assure the responsible person at the feeding station that the by-products are diclofenac-free. If needed the information could be used to trace back the origin of the by-products and to apply corrective actions.
Sampling scheme	Developing a sampling scheme for statistical purposes. The sampling scheme could be included as a condition on the marketing authorisation of veterinary medicinal products containing diclofenac; the marketing authorisation holder should bear all or part of the costs.	The sampling scheme would be useful for detecting an eventual breach of the protocols and for applying corrective actions. The information would provide a firm indication of whether exposure in the EU is likely and to predict its extent.
Withdraw veterinary diclofenac products from the EU market		Animal welfare would not be affected as alternatives are available. However, there still is a theoretical possibility of off-label use of human pharmaceutical products containing diclofenac.

*SPC: Summary of Product Characteristics.
Despite a risk having been clearly proven at the time of drafting the report in 2014, no diclofenac-related deaths of necrophagous birds have been reported in the European Union.

European surface water types (rivers, lakes, transitional, and marine water) per EU country (for further details and interactive concentration maps see Supplementary Information). The four most frequently detected NSAIDs were diclofenac, ibuprofen, ketoprofen and naproxen (Fig. 1). While diclofenac had the highest mean concentrations particularly in rivers and lakes, ibuprofen and naproxen were also commonly found, but typically at lower concentrations than diclofenac. Ketoprofen was frequently detected but in even lower concentrations (Fig. 1, Table S1).

Overall, the widespread occurrence and high levels of NSAIDs—primarily diclofenac, ibuprofen, naproxen, and ketoprofen—may pose a potential secondary-poisoning risk in piscivorous raptors and need further in-depth assessment. The evaluation of the actual impact of NSAIDs on affected populations of piscivorous raptors would require extended studies of these pharmaceuticals in environmental compartments and along the food chain. In regions where piscivorous raptors actually feed, the concentration of NSAIDs in fish should therefore be monitored. Considering seasonal and age-related migrations and high mobility of these raptors, more information on their actual exposure status and effects on population dynamics is needed in the future.

The risk of secondary poisoning was not among the questions that the EU Commission asked the EMA to address in its 2014 scientific opinion on risk of diclofenac to necrophagous birds. However, concentrations of diclofenac and other NSAIDs detected in surface waters over recent decades indicated a need to assess the risk of secondary poisoning for piscivorous raptors feeding on fish. We used the maximum of the average diclofenac concentrations by monitoring station measured in surface waters between 2003 and 2005 (Scheer, 2011) and the 95th percentile of measured concentrations in the period 2006 to 2019 (JRC, 2022). Based on these data, we estimated diclofenac concentrations in fish and compared the consumed diclofenac with its potentially safe concentrations for necrophagous birds from the EMA opinion (Kolar et al., 2014).

Secondary poisoning can occur when a predator consumes prey that has accumulated enough toxic chemical substances to induce intoxication. In the case of risk of secondary poisoning via contaminated fish, the piscivorous raptors of concern in Europe might be osprey (*Pandion haliaetus*) and white-tailed eagle (*Haliaeetus albicilla*), since they feed either solely or partly on fish (del Hoyo et al., 1994; Nadjafzadeh et al., 2016).

For the assessment of the risk of secondary poisoning for piscivorous raptors, we applied the methodology outlined in the EMA guidance

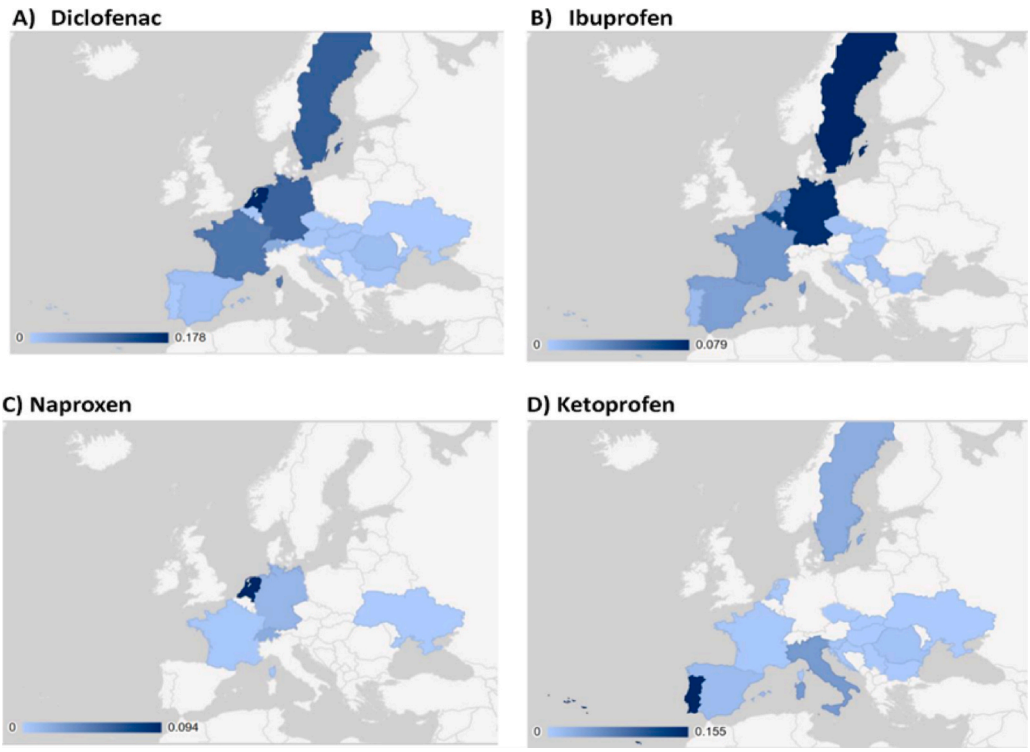

Fig. 1. Heatmaps of EU countries showing mean concentrations among all surface water types in μg/L for (A) diclofenac, (B) ibuprofen, (C) naproxen, and (D) ketoprofen for the years 2010–2020 reported in the NORMAN EMPODAT Database (NORMAN Network, 2026). For countries shaded in light grey, no information on NSAID concentrations was available.

(EMA/CHMP, 2024). Bioconcentration (BCF) and bioaccumulation (BAF) data serve as a screening trigger to determine whether secondary poisoning needs to be considered (BCF/BAF $\geq$ 100) and are also used to quantify $PEC_{fish(oral,predator)}$. If triggered, the risk is evaluated using the risk quotient (RQ) approach, defined as the ratio between the predicted environmental concentration in prey fish ($PEC_{fish(oral,predator)}$) and the predicted no-effect concentration for predators ($PNEC_{oral,predator}$). The $PEC_{fish(oral,predator)}$ is calculated using Equation (1):

$$PEC_{fish(oral,predator)} = PEC_{sw} \times BCF_{fish} \times BMF \quad (1)$$

where PEC_{sw} is the predicted concentration in surface water, BCF_{fish} (or BAF_{fish}) is the bioconcentration factor (or bioaccumulation factor) for fish, and BMF is the biomagnification factor.

The octanol–water partitioning coefficient (log K_{OW}) of diclofenac is 4.02 (Scheer, 2022), indicating its potential for bioaccumulation. The highest reported experimental BAF for molluscs was 216 L/kg (Scheer, 2022). Although high-quality data from Scheer (Scientific Committee on Health, Environmental and Emerging Risks) were used, uncertainty remains, as BAF values could be significantly higher according to the available literature (Armitage et al., 2017; Mueller et al., 2020). This uncertainty mainly arises from the ionisable nature of diclofenac, as pH-dependent dissociation can considerably influence its partitioning behaviour and bioaccumulation potential (Kroll et al., 2024). Based on the maximum mean diclofenac concentration of 0.71 μg/L (Scheer, 2011) and the 95th percentile concentration of 0.28 μg/L (JRC, 2022), together with BAF of 216 L/kg (Scheer, 2022), the calculated $PEC_{fish(oral,predator)}$ were 153 μg/kg and 60.5 μg/kg, respectively. These estimated concentrations of diclofenac in fish were then used to assess the risk of secondary poisoning for piscivorous raptors.

To derive the $PNEC_{oral,predator}$, the lowest available LD_{50} for vultures (0.225 mg/kg bw/d) was used. From this value, an LC_{10} of 0.343 mg/kg feed was calculated (see chapter 'Toxicity of diclofenac to necrophagous birds'). Based on the protection goal to protect individuals rather than populations or communities, and to ensure the safety of potentially exposed avian scavengers and piscivorous raptors, an assessment factor of 100 was applied (Kolar et al., 2014). This AF accounts for interspecies differences in sensitivity as well as for variability between different life stages within a species. The corresponding $PNEC_{oral,predator}$ was 3.4 μg/kg feed.

The calculated risk quotient (RQ) of 45, based on monitoring data from 2003 to 2005 (Scheer, 2011), confirms a high risk of secondary poisoning for necrophagous and piscivorous raptors via the aquatic food chain. When more recent monitoring data from JRC (2022), measured between 2006 and 2019, are used, the resulting RQ decreases to 18. This reduction is consistent with the lower diclofenac concentrations measured in surface waters in the later monitoring period compared with the earlier dataset, indicating that measures implemented to reduce diclofenac emissions to the aquatic environment have been at least partially effective. However, despite this improvement, the risk for piscivorous birds remains unacceptably high, highlighting the need for further mitigation measures.

Diclofenac and other NSAID concentrations detected in European surface waters may therefore continue to pose a substantial threat to both necrophagous and piscivorous raptors.

4. Population trends and status of vulture populations in Europe

European vulture populations have declined over the last century, mainly driven by poisoning, persecution, electrocution, and collisions (Ogada et al., 2022). This presents an emerging concern in terms of species conservation and maintenance of the ecosystem services they provide. Consequently, conservation measures such as supplementary feeding were implemented to curb declining trends. As a result, vulture populations in Europe have increased to 34,800–44,700 breeding pairs of griffon vulture (*Gyps fulvus*), 3,000–4,000 Egyptian vulture (*Neophron percnopterus*), 2,900–3,400 cinereous vulture (*Aegypius monachus*), and 630–960 bearded vulture (*Gypaetus barbatus*), which can be translated into ~ 81,000–105,000 mature vultures distributed mainly throughout

southern Europe (BirdLife International, 2021a,b,c,d). Regarding long-term population trends, except for griffon vultures, which experienced a clear increase, there is a general declining tendency in European vulture populations. In some species, such as the Egyptian vulture, this reaches estimates of 79 % of population loss in three generations (53 years) (BirdLife International, 2021a,b,c,d). For the four species present, Spain represents the main stronghold for European vulture populations, holding 90 % of griffon vulture and cinereous vulture populations, 32 % of the Egyptian vulture population, and 15 % of the bearded vulture population (Del Moral, 2017; Del Moral and Molina, 2018; Margalida and Martínez, 2020). In this context, translocation efforts have been established as a method to trigger the settlement of griffon and cinereous vultures in European regions with struggling populations, which is especially relevant for endangered species. According to the IUCN Red List, all the European vultures except griffon vultures (*Gyps fulvus*) present a fragile conservation status: the cinereous vulture (*Aegypius monachus*) is decreasing, the Egyptian vulture (*Neophron percnopterus*) is endangered, and the bearded vulture (*Gypaetus barbatus*) is considered near threatened in Europe and endangered in the Mediterranean (IUCN, 2026).

5. Efficacy of existing risk-management measures (RMM) and their related uncertainties: A case study from Spain

Following the authorisation of diclofenac for veterinary use in Spain, mitigation measures were taken to restrict the exposure to diclofenac through contaminated carcasses. The main measure was to add a warning in the package leaflet of the drug advising on the high toxicity of diclofenac to *Gyps* vultures, which was also added later for flunixin after the detection of griffon vulture deaths due to this NSAID (AEMPS, 2014). This was promoted by the Spanish Agency of Medicines and Sanitary Products (AEMPS) and was meant to inform veterinarians, the only professionals allowed to administer these NSAIDs to domestic animals in farms. The Spanish case can be interpreted as a case study regarding the importance of the vulture population hosted by this country and the authorisation of diclofenac 10 years prior to the risk-management measures. The effectiveness of this measure is difficult to estimate since the veterinary use of diclofenac in farms is private, although farmers must have an internal register of all the veterinary products they administer (Herrero-Villar et al., 2024). Thus, there are no available data on the actual use of diclofenac or other toxic NSAIDs and pharmaceuticals for avian scavengers. Nevertheless, at least two pig carcasses (out of 249 in total) have been identified with diclofenac residues (0.004–0.17 mg/kg) and supplied at feeding stations for vultures, which indicates that diclofenac is used, and that exposure can occur (Herrero-Villar et al., 2023, 2020). Further, other NSAIDs like flunixin have been reported in domestic animal carcasses, mainly in pigs and sheep, some containing lethal concentrations for vultures (27.5 mg/kg) (Herrero-Villar et al., 2020). Importantly, carcasses were sampled on randomly selected days without prior notification to farms or farmers, minimizing the possibility that carcass management practices were altered in anticipation of sampling.

The documented diclofenac intoxication of a cinereous vulture (Herrero-Villar et al., 2021a) shows that the existing mitigation measures did not fully prevent exposure and poisoning of individual birds; on its own, however, this single case does not allow for conclusions to be drawn on the level of protection achieved at the population level. Precisely, this incident occurred in a reintroduction colony, closely monitored and designed as an ecological corridor for the species to other European regions. The finding is particularly concerning as it is the first case of a cinereous vulture in Europe poisoned by diclofenac; so far this had been reported from South Asia only (Oaks et al., 2004). In addition to diclofenac, flunixin intoxication cases have been reported in at least five griffon vultures in Spain. Flunixin residues have been found in plasma and liver from deceased griffon and Egyptian vultures at low levels, which provides evidence for exposure (Herrero-Villar et al., 2020, 2023; Zorrilla et al., 2015).

So far, only a low number of diclofenac and other NSAID poisoning events have been documented in Europe. However, we must consider that vulture monitoring is challenging because they inhabit remote and inaccessible areas, and because they can travel long distances after exposure, which may make them difficult to locate after feeding on the carcasses of intoxicated animals. It is evident that stronger efforts are needed in terms of monitoring vulture carcasses in Spain and especially in countries with fragile populations where NSAID poisoning impacts can be critical. Furthermore, there is uncertainty regarding the toxicity thresholds that may lead to vulture poisoning in certain species such as the bearded vulture or the Egyptian vulture, both of which are among the most vulnerable vulture species in Europe.

In Spain, domestic animal carcasses are disposed of following regional regulation, which permits the removal of these carcasses at supplementary feeding stations or being left in the field. However, there is no mandatory process to ensure that these carcasses are NSAID-free. This type of management, together with the vast mass of domestic animal carcasses disposed of in the field, makes it difficult to prevent the release of contaminated tissues to the field. In addition, there is no measurement of the level of awareness veterinarians or farmers have currently of the ecological consequences of disposing carcasses containing residues of pharmaceuticals to the field. Finally, no active pharmacovigilance measures have been implemented since the authorisation of diclofenac (or other pharmaceuticals) in Spain in terms of continued field monitoring to promptly detect residues as a prevention measure against intoxication.

6. Recommendations for further risk-management strategies with the implications for conservation

6.1. Improvement of risk assessment for necrophagous and piscivorous raptors

The risk-management strategy aims to mitigate the risk for necrophagous birds and is based on the premise that the legal commitments bind the marketing authorisation holder and the national competent authority to ensure that the use of NSAIDs, including diclofenac and other veterinary pharmaceuticals, will not pose a risk for necrophagous birds. All VMP authorisation procedures should assess the risk of products previously identified as toxic or suspected to have a physiological impact on necrophagous birds. The *ad hoc* risk assessment methodology used in the ERA for diclofenac in 2014 (Kolar et al., 2014) provides a solid ground for the development of respective guidelines. In addition to existing methods, new approach methodologies (NAMs) in identifying toxicological thresholds could be of valuable support. Regarding the protection of raptors and vultures, such NAMs could be integrated with species-specific pharmacokinetics, carcass-based exposure scenarios and mixture occurrence data to move towards more realistic prospective risk assessment and management for multiple exposures to pharmaceuticals. Recent syntheses on pharmaceuticals in avian scavengers and other birds of prey highlight that current regulatory ERAs rarely address long-term or sublethal effects, mixture toxicity or age/condition-dependent sensitivity, and call for NAM-based frameworks that integrate updated pharmacokinetic data, biomarkers of renal and immune function, and population-level models tailored to vultures and raptors (Herrero-Villar et al., 2024).

NSAIDs are widely used in human medicine and are regularly monitored and commonly detected in surface waters of EU member states. Substances such as ibuprofen and diclofenac are found at concentrations that pose a risk to the aquatic environment and, consequently, both substances are on the updated list of priority substances of the Water Framework Directive, and measures must be taken to reduce their concentration in surface water (EC, 2000, 2026).

The assessment provided in the current study of the potential for secondary poisoning is based on the detected concentrations of

diclofenac in surface waters. A risk is identified for vultures feeding on fish carcasses and can be extended to other potentially affected fish-eating raptors such as osprey and white-tailed eagles. The assessment of secondary poisoning conducted in this article resulted in a high risk-quotient, highlighting the need for field surveys and targeted monitoring of diclofenac in fish and tissues of exposed birds in river sections known to have a history of diclofenac pollution. These findings also add a new perspective on the potential impact of NSAIDs in the EU environment, as the protection of top raptors in the EU requires a holistic approach, potentially including legislative changes (Gildemeister et al., 2023; Treu et al., 2022). The identified risk of secondary poisoning through the food chain based on data from two decades of monitoring of EU surface waters indicates a need to include piscivorous raptors as a protection goal of ERA for NSAIDs used in human medicine.

The most challenging aspect may be securing cross-sector collaboration, as demonstrated by the implementation of risk-management measures proposed by the EMA. Namely, at the time of the Commission referral on diclofenac all authorisations were carried out under the national procedure, in which the national authorities are responsible for preparing and implementing risk-management measures. Evaluation of the effectiveness of measures taken in Spain over the past decade showed several inconsistencies that resulted in an unacceptably high number of carcasses exposed to necrophagous birds that contained NSAIDs, resulting in the death of a cinereous vulture due to intoxication with diclofenac. As such, the adequate management of potentially contaminated animal carcasses in EU member states with smaller, and therefore more vulnerable, subpopulations of vultures might be crucial for the survival of necrophagous avifauna.

6.2. *Monitoring and surveillance programmes of diclofenac and other NSAIDs that might pose a risk for necrophagous birds in veterinary and human medicine*

Experiences from the implementation of RMMs in Spain revealed an urgent need to monitor both domestic animal carcasses and deceased vultures regularly to map the real risk of diclofenac and other pharmaceuticals. Effective monitoring systems for ecopharmacovigilance of NSAIDs in Europe should incorporate specialised surveillance programmes tracking pharmaceutical residues in necrophagous birds and their food sources, as demonstrated by Spain's comprehensive monitoring scheme which includes both carrion analysis at supplementary feeding stations and toxicological surveillance of dead vultures collected from wildlife recovery centres (Moreno-Opo et al., 2021). Other measures such as monitoring vulture population status regularly among different regions and countries can also be useful to promptly detect declining trends and identify the areas that may need stronger conservation efforts (Herrero-Villar et al., 2024). Monitoring is crucial to detect NSAID—and other pharmaceuticals—intoxication cases in avian scavengers but also to ensure compliance with regulations that seek to prevent exposure. Currently, the only existing RMM in the EU is the warning to veterinarians that has been added in the package leaflets of diclofenac and flunixin, but there is no mandatory commitment binding to this recommendation. Regulation compliance together with awareness of the main actors responsible for domestic animal carcass management (i.e., veterinarians and farmers) is essential to mitigate the risk of NSAID and other pharmaceuticals in scavenging wildlife.

6.3. *Public awareness campaigns*

Targeted and sustained public-awareness campaigns will be important in reducing exposure of European necrophagous birds to NSAIDs (Safford et al., 2019). These communication efforts should prioritise veterinarians, farmers, slaughterhouse operators, and managers of supplementary feeding stations, using clear and scientifically informed messaging. In this regard, it would be beneficial for communication materials to be co-branded with veterinary associations and/or relevant authorities, and delivered via continuing professional development, drug wholesalers' ordering portals, on-pack/leaflet warnings, and signage at carcass drop-off points and feeding stations. A 'One Health' framing can be used to emphasise that small changes in prescribing, record-keeping, and carcass routing will prevent mortality events in threatened raptors and protect the ecosystem services provided to humans by vultures (Bertram et al., 2024).

The awareness campaign should also recognise that many farmers in the Mediterranean, the Pyrenees, the Apennines, and Balkan countries still farm traditionally. Therefore, the campaign in those rural areas should focus on personal communication between veterinarians and farmers. This is especially relevant in those countries that hold small populations like those established in Balkan countries, where exposure to pharmaceuticals can pose an extra pressure.

To increase the effectiveness of public-awareness campaigns, they could pair education with simple tools such as QR-coded farm posters leading to carcass-eligibility checklists, labelling systems for contaminated by-products, and a phone number or mobile application to report suspect carcasses or unwell birds (Herrero-Villar et al., 2021b, 2020). Effectiveness should be audited with pre- and post-knowledge surveys of veterinarians and farmers, counts of correctly documented carcasses, and trends in NSAID residue detections and wildlife intoxications, which will enable adaptive refinement. Such campaigns complement regulatory RMMs and monitoring by closing the gap between prescription, carcass fate, and exposure status of necrophagous raptors.

7. Conclusion

In the European context, the risk assessment of diclofenac to necrophagous birds provided by EMA concluded that risk cannot be excluded when diclofenac is used in cattle, pigs, and sheep. Risk-mitigation measures based on safe diclofenac threshold concentrations were proposed to national authorities. However, a review of the effectiveness of risk mitigation in Spain revealed deficiencies in the RMM, particularly with regard to NSAIDs in animal carcasses exposed to scavengers and NSAID residues in necrophagous birds. A decade of post-assessment evidence, including measured NSAID residues in domestic animal carcasses and in vultures, demonstrates that exposure continues even in the absence of mass mortalities. From a regulatory perspective, this means that an identified risk has not been fully translated into effective protection through the ERA methodologies for VMPs. For piscivorous raptors, our analysis indicates that the exposure route via feeding on contaminated fish and related risks are not sufficiently captured by the existing regulatory framework. Consequently, substances previously identified or known to be toxic for avifauna such as NSAIDs need to be assessed, or reassessed when new evidence emerges, to determine whether their use in veterinary and human medicine would pose a risk to necrophagous and piscivorous raptors. We therefore propose that when indicated, necrophagous and piscivorous raptors should be explicitly included as a protection goal during the authorisation procedure of veterinary and human pharmaceuticals. To implement this, no new general legal provisions are needed as the actual guideline implicitly mentions special eventualities and potential case-by-case situations, going beyond the standard procedures, already in the introduction and in the general scope (VICH, 2000; VICH, 2004; EMA/CHMP, 2024).

Based on the risk identified, a risk-mitigation management plan should be endorsed considering legal provisions as well as public awareness of toxicity to species at risk. In summary, we stress that potential future NSAID-driven raptor crises in Europe can be prevented only by combining regulatory, technical, and social measures addressing both veterinary and human NSAID uses, and both terrestrial and aquatic exposure routes. ERA frameworks should be further strengthened and explicitly cover necrophagous and piscivorous raptors. Further, they should link to enforceable risk-management plans that regulate carcass routing, feeding station operations, and River Basin Management Plans.

In this sense, top-down measures need to be complemented by bottom-up public awareness campaigns targeting veterinarians, farmers, slaughterhouse operators, and managers of feeding stations, supported by practical tools to identify and divert high-risk carcasses. Additionally, sustained monitoring of domestic carcasses, surface waters, fish, and avian scavengers will be required to assess the effectiveness of these interventions and adaptively refine policy with the goal of safeguarding Europe's raptor populations and the vital ecosystem services they provide.

CRediT authorship contribution statement

Boris Kolar: Writing – review & editing, Writing – original draft, Investigation, Funding acquisition, Conceptualization. **Nikiforos Alygizakis:** Writing – review & editing, Visualization, Formal analysis. **Michael G. Bertram:** Writing – review & editing, Writing – original draft, Investigation, Funding acquisition, Conceptualization. **Marta Herrero-Villar:** Writing – review & editing, Writing – original draft. **Gerd Maack:** Writing – review & editing. **Gabriele Treu:** Writing – review & editing, Writing – original draft, Visualization, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Mojca Durjava:** Writing – review & editing, Writing – original draft, Investigation, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

NSAID concentrations in European surface waters. Summary statistics for 15 NSAIDs measured between 2010 and 2020 (Table S1), an interactive heatmap of nine NSAIDs (Data S1), and the R script used for data processing (Data S2). Supplementary data to this article can be found online at https://doi.org/10.1016/j.envint.2026.110575.

Data availability

All data used in this study were obtained from publicly available sources, including the NORMAN EMPODAT database and published JRC and SCHEER reports.

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