

Einführung

Kathrin Begemann

Vergiftungs- und Produktdokumentation – Wofür?

Giftberatung / Klinische Toxikologie



- **GIZ:** ~ 250.000 Fälle/Jahr
 - ~ 25-30 % chemische Produkte

Regulatorische Toxikologie



Europäische Kommission



Bundesministerium
für Umwelt, Naturschutz,
Bau und Reaktorsicherheit



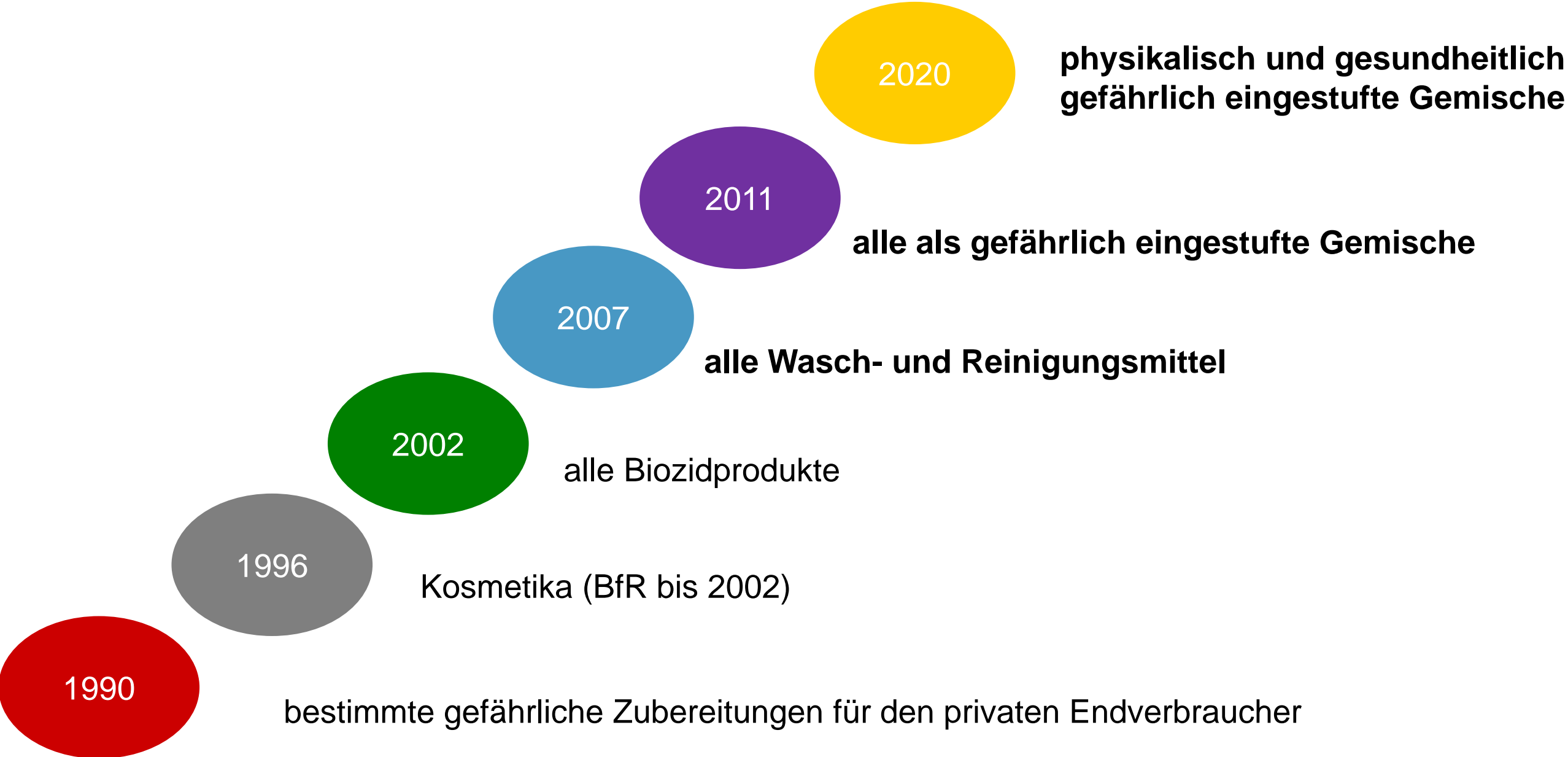
Bundesministerium
für Ernährung
und Landwirtschaft



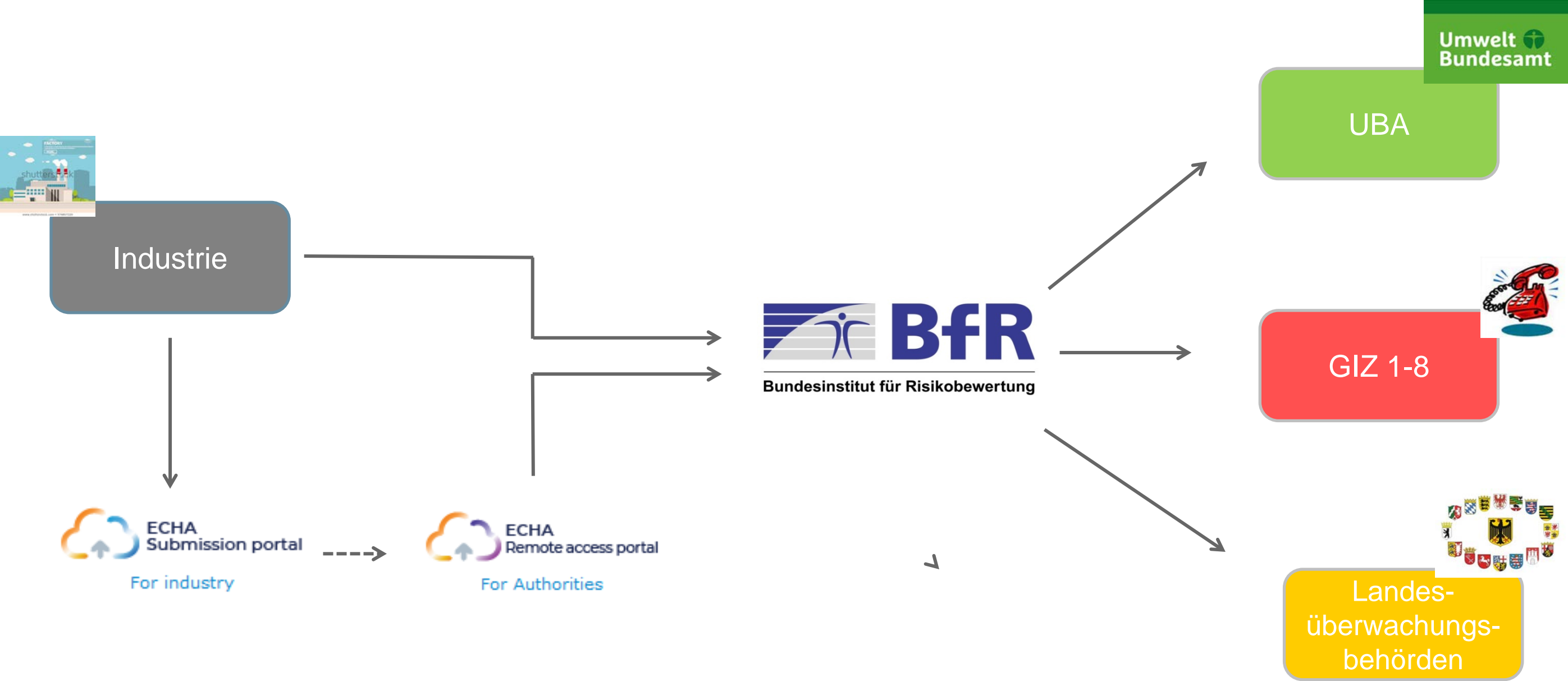
Bundesinstitut für Risikobewertung

- **BfR:** ~ 8.000 Fälle/Jahr
 - ~ 99 % chemische Produkte

Gesetzliche Meldepflicht für Produkte zur med. Notfallberatung



Meldewege für Produktinformationen in Deutschland



PCN-Mitteilungen an das BfR



Overview of Member States decisions in relation to implementation of Annex VIII to CLP Regulation (Poison Centre Notification)

November 2019

Overview of Member States decisions in relation to implementation of Annex VIII to the CLP Regulation (Poison Centre Notification) - version 2.1 (04.11.2019)

Disclaimer: The information is based on input from Member States. The declarations of Member States are indicative and subject to changes. ECHA aims at updating this document to reflect the latest status. For further information, please contact national CLP Helpdesk <https://echa.europa.eu/support/helpdesks/>.

Member State	Submission portal	Readiness of Member State to accept notifications via ECHA submission system	Notification language	Fees for notifications	Placing on the market mixtures notified via ECHA submission system	Member State
	Member State accepts notifications only via ECHA submission system	Member State already connected to ECHA submission system and duty holders can start notifying their mixtures	Duty holder may choose notification language between official language of the Member State or English (includes Member States where English is official language)	No fees	Duty holder can start placing mixture on the market immediately after confirmation of successful submission by the ECHA submission system (without awaiting approval from Member State)	
	Member State accepts notifications via national submission system or ECHA submission system (duty holder has discretion of choice)	Duty holders must continue to notify their mixtures according to national legislation until further notice	Duty holder must notify in one official language of the Member State (other than English)	Fees levied by Member State appointed body	Duty holder can start placing mixture on the market only after the Member State appointed body has downgraded the notification (information varies to duty holder in the submission report of ECHA system)	
			Duty holder must notify in multiple official languages of the Member State (other than English)	Fees under consideration		
	No information available	No information available		No information available	No information available	
Austria			German			Austria
Belgium			French or Dutch or German or English			Belgium
Bulgaria			Bulgarian			Bulgaria
Croatia			Croatian or English			Croatia
Cyprus			Greek			Cyprus
Czech Republic			Czech			Czech Republic
Denmark			Danish or English			Denmark
Estonia			Estonian or English			Estonia
Finland			Finnish and Swedish			Finland
France			French			France
Germany			German or English			Germany
Greece			Greek			Greece
Hungary			Hungarian			Hungary
Iceland			Icelandic			Iceland
Ireland			English			Ireland
Italy			Italian or English			Italy
Latvia			Latvian or English			Latvia
Liechtenstein			German			Liechtenstein
Lithuania			Lithuanian or English			Lithuania
Luxembourg			French or German or English			Luxembourg
Malta			Maltese or English			Malta
Netherlands			Dutch or English			Netherlands
Norway			Norwegian or Danish or Swedish or English			Norway
Poland			Polish			Poland
Portugal			Portuguese			Portugal
Romania			Romanian			Romania
Slovakia			Slovak			Slovakia
Slovenia			Slovenian			Slovenia
Spain			Spanish or English			Spain
Sweden			Swedish or English			Sweden
United Kingdom			English			United Kingdom

Für Deutschland gilt:

- ❖ Meldung über PCN-Portal (ECHA) **oder** direkt an das BfR
- ❖ Annahme der PCN-Produktmeldungen seit April 2019
- ❖ Deutsch und Englisch
- ❖ Keine Gebühren
- ❖ Produkt kann auf den Markt gebracht werden, wenn die Mitteilung im BfR vorliegt

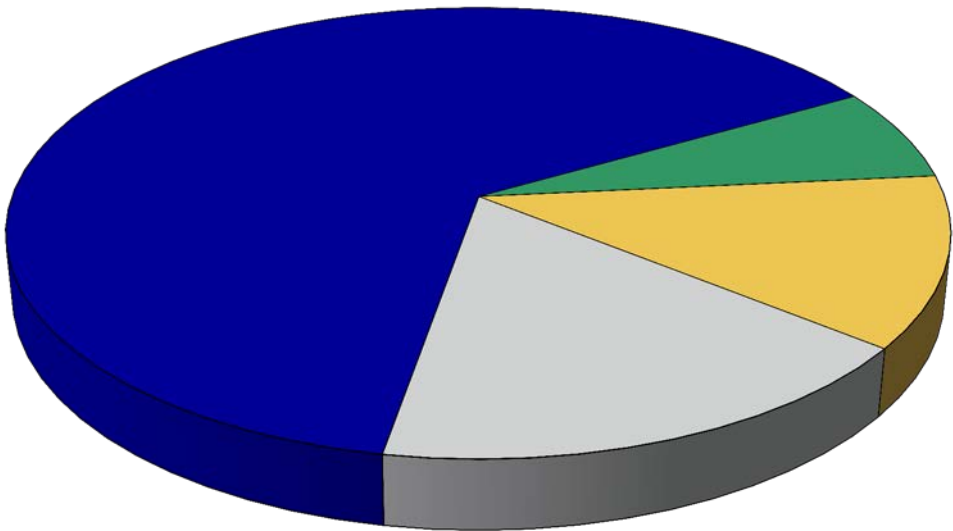
Implementierung des Formates nach CLP Anhang VIII in Deutschland

- Übernahme der PCN-Mitteilungen (.i6z Dateien) in die BfR-Produktdatenbank seit April 2019
- Weiterleitung der Produktmitteilungen an die deutschen GIZ ab 1. Dezember 2019

- **ECHA**: Validation-Assistent für technische Qualitätssicherung
- Benannte Stellen/**BfR**: inhaltliche Qualitätssicherung

- Kein BfR-Datenerfassungsprogramm für das neue harmonisierte Format
- Mitteilungseditor (in IUCLID 6) wird benötigt, sofern nicht automatisierte Erstellung der Meldung

Produkt-Datensätze in der Giftinformationsdatenbank (Stand: 31.10.2019)



- Gesamt**
ca. 468.100

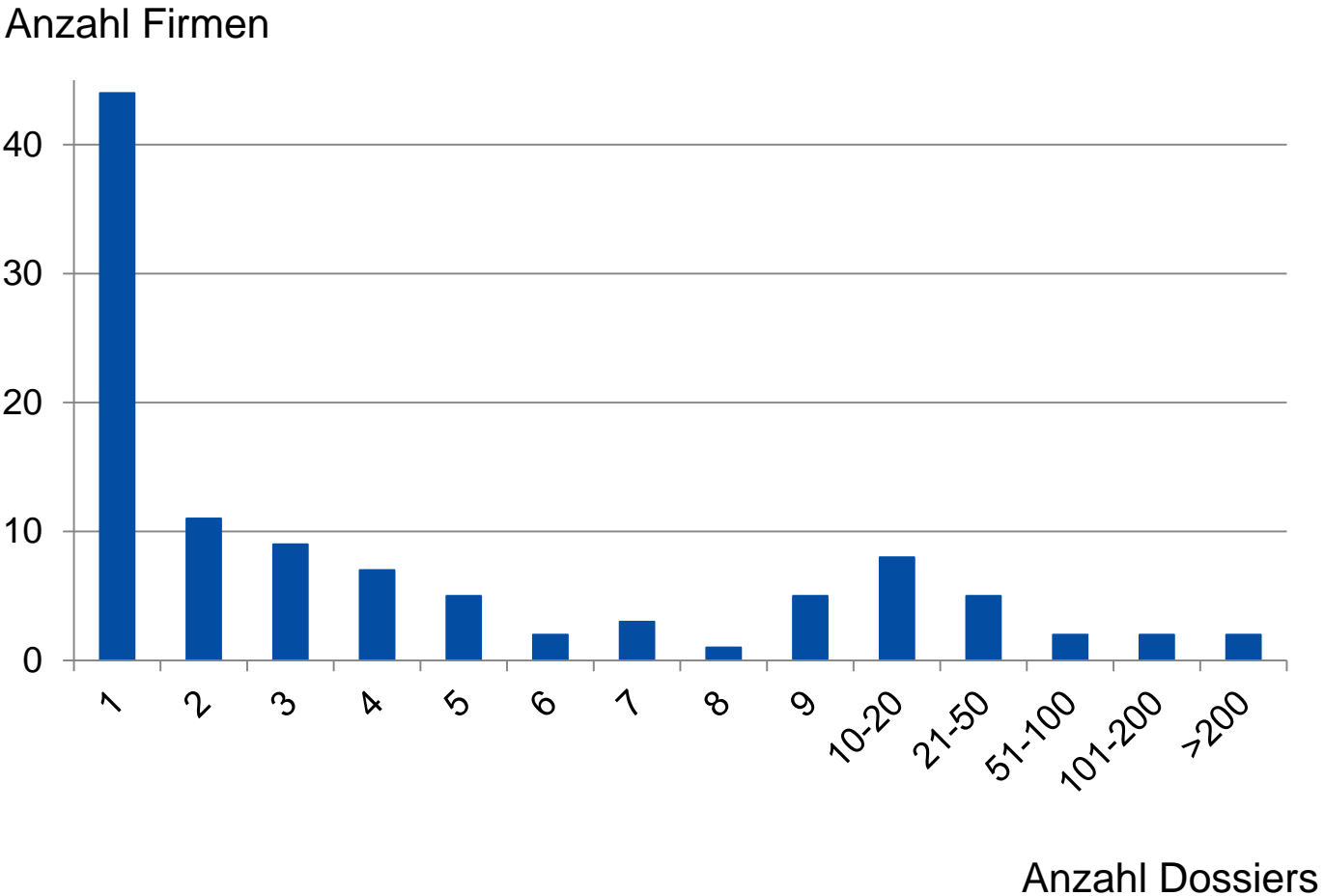
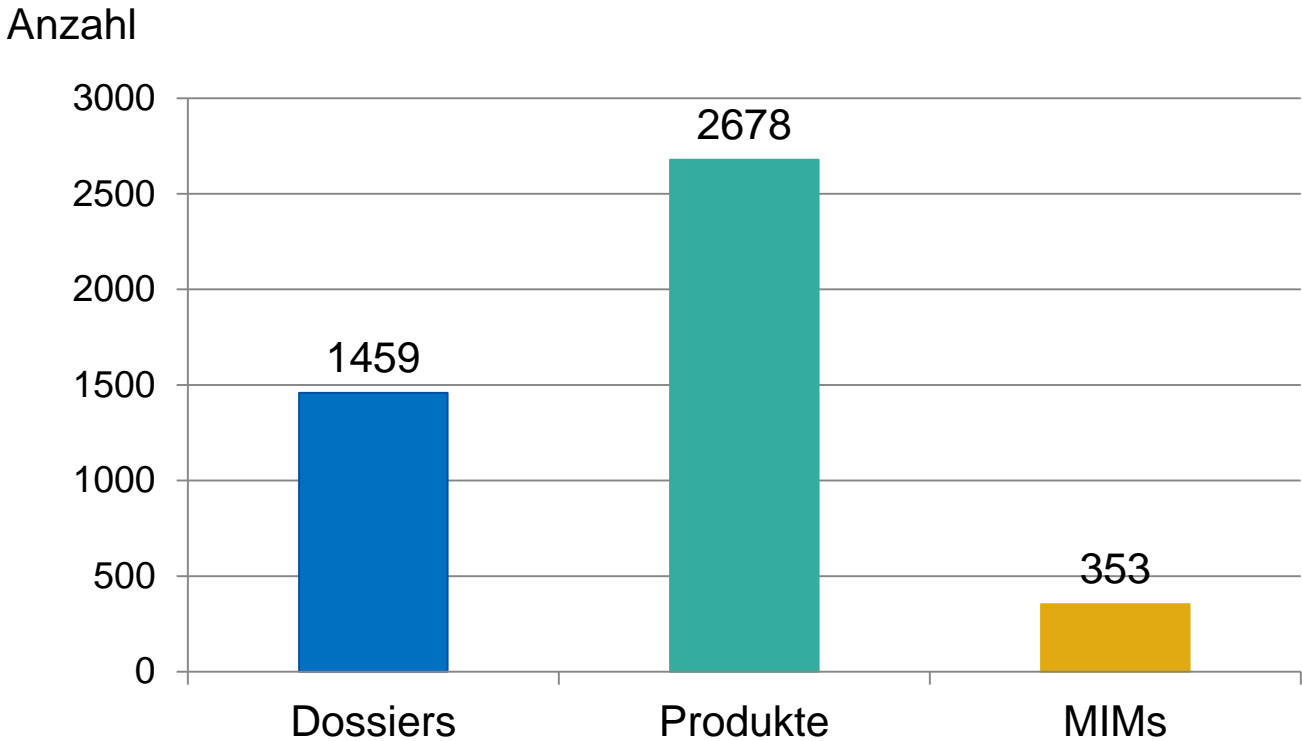
- Gefährliche Gemische**
ca. 299.700
davon ca. 48.100 „WRMG-Meldungen“
- Biozide**
ca. 31.200
- Wasch- und Reinigungsmittel**
ca. 57.200
- Freiwillig gemeldet**
ca. 80.000

+ ca. 4,5 Mio Sicherheitsdatenblätter

Produktmitteilungen über das PCN-Portal der ECHA für Deutschland

01.05.2019 bis 14.11.2019

Mitteilungen von 106 Firmen



Programm

Produktmitteilungen aus Sicht des Giftinformationszentrums Mainz

Andreas Stürer

Product Notifications according Article 45 CLP in Ireland

Edel Duggan

Annex VIII CLP-Regulation and Product Notifications via the PCN-Portal (ECHA)

Daniele Ape, ECHA

Ergebnisse der EU-Machbarkeitsstudie

Kathrin Begemann

Datensicherheit am BfR

Christoph Möhring

FAQ

Ronald Keipert, Esther Feistkorn

10. BfR-Nutzerkonferenz
zu Produktmeldungen

18. November 2019, Berlin



Danke für Ihre Aufmerksamkeit

Kathrin Begemann

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