An Roinn Talmhaíochta,
Bia agus Mara
Department of Agriculture,
Food and the Marine

Enforcement of the BPR in Ireland

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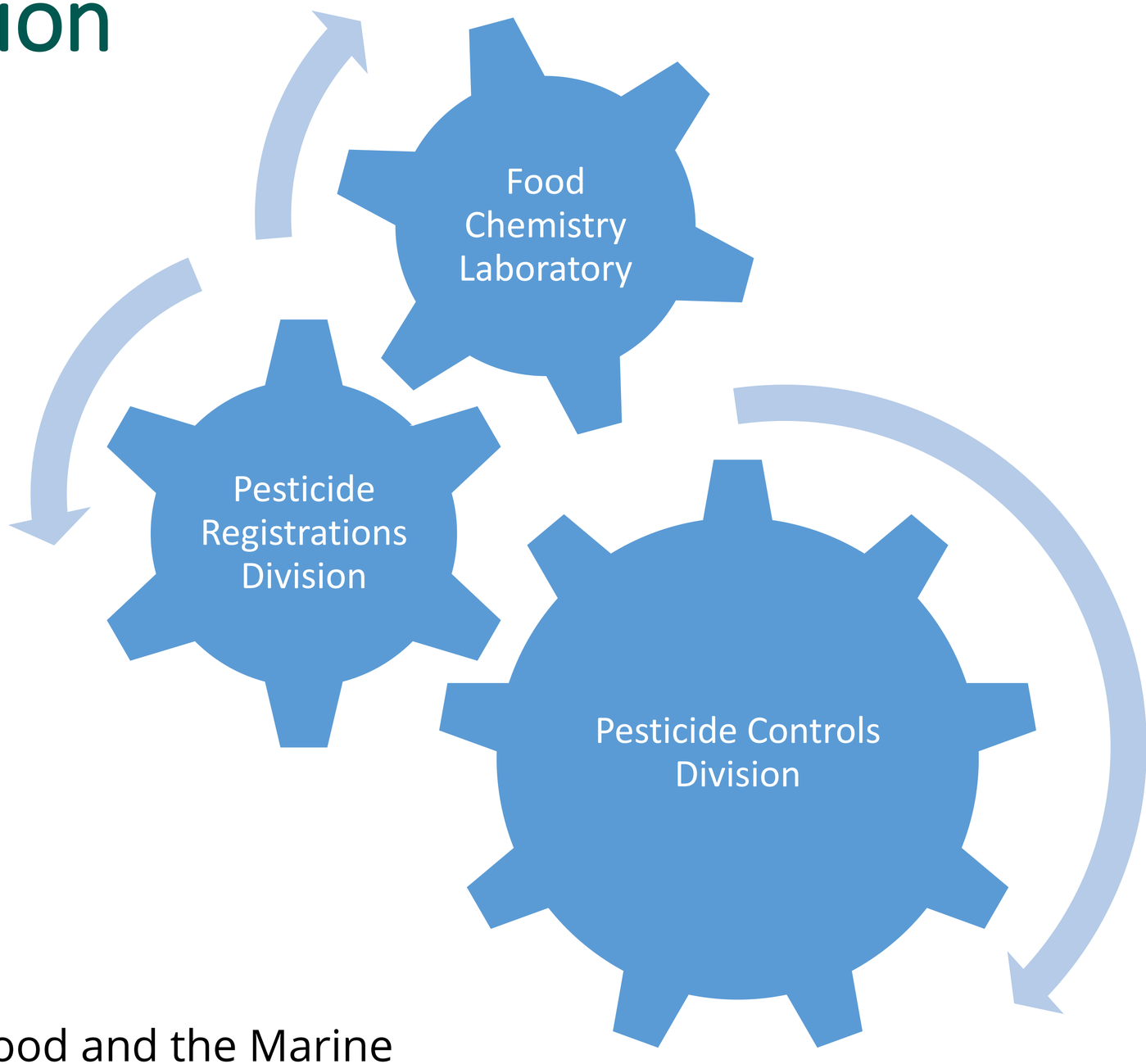
General Introduction and Legislative background

Pesticide Controls Division

Responsible for all legislation related to Pesticides

Work closely with other DAFM* colleagues;

- Pesticide Registrations Division,
  - Evaluation of dossiers (eCA),
  - Peer-Review as cMS
- Food Chemistry Laboratory
  - Pesticide residues in food
  - Formulation testing of products



*DAFM - Department of Agriculture, Food and the Marine

Legislative Responsibilities - Biocides

- Responsible for the pesticide elements of the following pieces of legislation
  - **Biocidal Products Regulation - 528/2012/EC**
  - REACH Regulation - 1907/2006/EC
  - CLP - 1272/2008/EC
  - PIC – 649/2012 - Rotterdam Convention
  - POP – 2019/1021/EC - Stockholm Convention
  - MSR – 2019/1020/EC
  - GPSR – 2023/988/EC
  - DSA – 2022/2065/EC

Enforcement Linkages within DAFM

Controls are carried out across DAFM Divisions on food business operators and at farm level for food safety, animal health, plant health and animal welfare.

Biocides are critical in the control of harmful organisms for the protection of man, animals and the environment and used across all sectors.

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Enforcement Linkages in Ireland

Work closely with following authorities with shared responsibilities on legislation and borderline products

- Health and Safety Authority (HSA) – industrial chemicals, detergents
- Health Products Regulatory Authority (HPRA) – Human Medicines, Medical Devices, Veterinary medicines, Cosmetics
- Environmental Protection Agency (EPA) – MOU for PT 5 enforcement
- Food Safety Authority (FSAI) – residues
- National Poison's Information Centre (NPIC)
- General Product Safety Regulation Network

European linkages in Europe

- FORUM BPR-S – The BPR Subgroup of the Forum for Exchange of Information on Enforcement
- 27 EU Competent Authorities
- ECHA HelpNet – Network of ECHA, REACH, CLP and BPR helpdesks
- Safety Gate Tool – EU Rapid Alert system

Market Surveillance

Registration of pesticides in Ireland

	Registrations
Notified Biocides (Art 89)	3248
Authorised Biocides (Art 19)	888
Simplified Authorisations (Art 25)	19
PPP	1251
Total Pesticides	5406

Market Surveillance of Pesticides

PCD operates the enforcement program for pesticides

- biocides
- PPPs

Historically, PPP the primary focus as they were authorised

Focus has moved to include Biocidal products also.

Role of Enforcement Officer

Enforcement of pesticide legislation

- Making available on the market at distributor, wholesale & retail level
- Packaging & labelling of pesticides
- Formulation testing – confirming registered formulation
- Pesticide residues
- End-user inspections - ensure proper storage and use

Education and awareness raising

- Speaking at information meetings

Authorised Officers

Officers are authorised to inspect and perform their duties on the basis of Statutory Instruments:

- S.I. 427 of 2012 (Biocidal Products Regulation);
- S.I. 159 of 2012 (PPP Regulation);
- S.I. 155 of 2012 (SUD of pesticides)
- S.I. 565 of 2008 (Pesticide Residues)
- The Chemicals Act 2008, as amended by the chemicals (Amendment Act) 2010
- S.I. 511 of 2008 (The Poisons Regulation 2008)

Powers of Authorised Officers

- Enter and search a premises
- Stop a person, vehicle, vessel or container
- Board and search a vehicle, vessel or container
- Examine a product (or other thing)
- Take samples
- Require the production of documents/records
- Retain documents
- Record or take photographs
- Give direction
- Require the name and address and ownership details
- Issue compliance notices
- Issue fixed penalty notices

Sanctions Available to DAFM

- Require product to be removed from shelves;
- Destruction of product (at owners expense);
- Issue compliance notice (action required within specified timeframe)
- Issue fixed penalty notice
- Prosecution = fine/jail

At a minimum, failure to comply can result in considerable time and financial costs, far in excess of the time (and cost!) involved in registration

Checks Carried out during Routine Inspection

Marketing

- Are all products present notified, authorised or permitted?
- If the product has an approval no, is it identical to details on register?
- Are product labels compliant?

Use

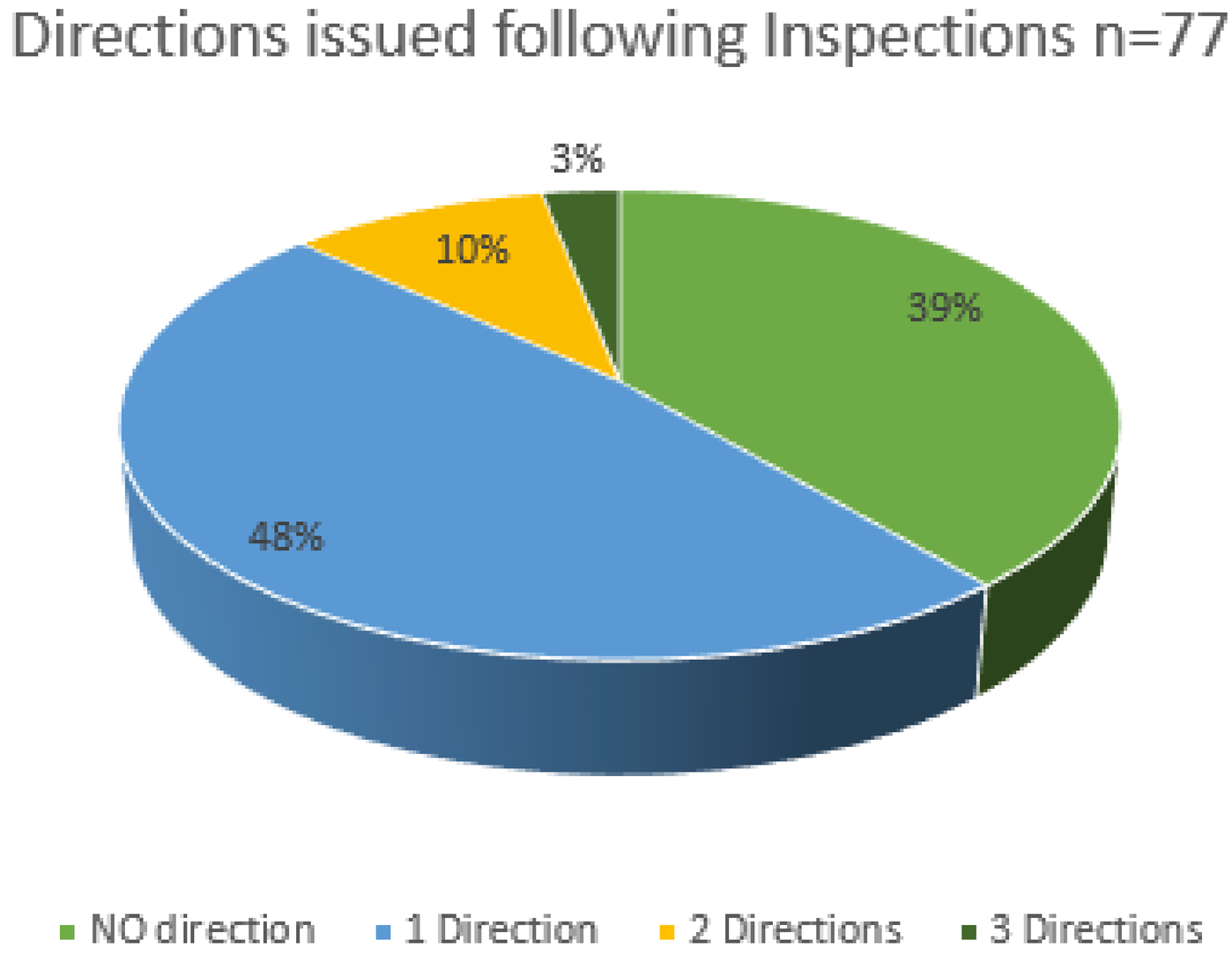
- Are products stored in a safe and appropriate manner?
- Are products being used in accordance with label instructions?
- Are records being maintained, and do they indicate that product is being used according to the label recommendations?

Enforcement Action Taken To-date

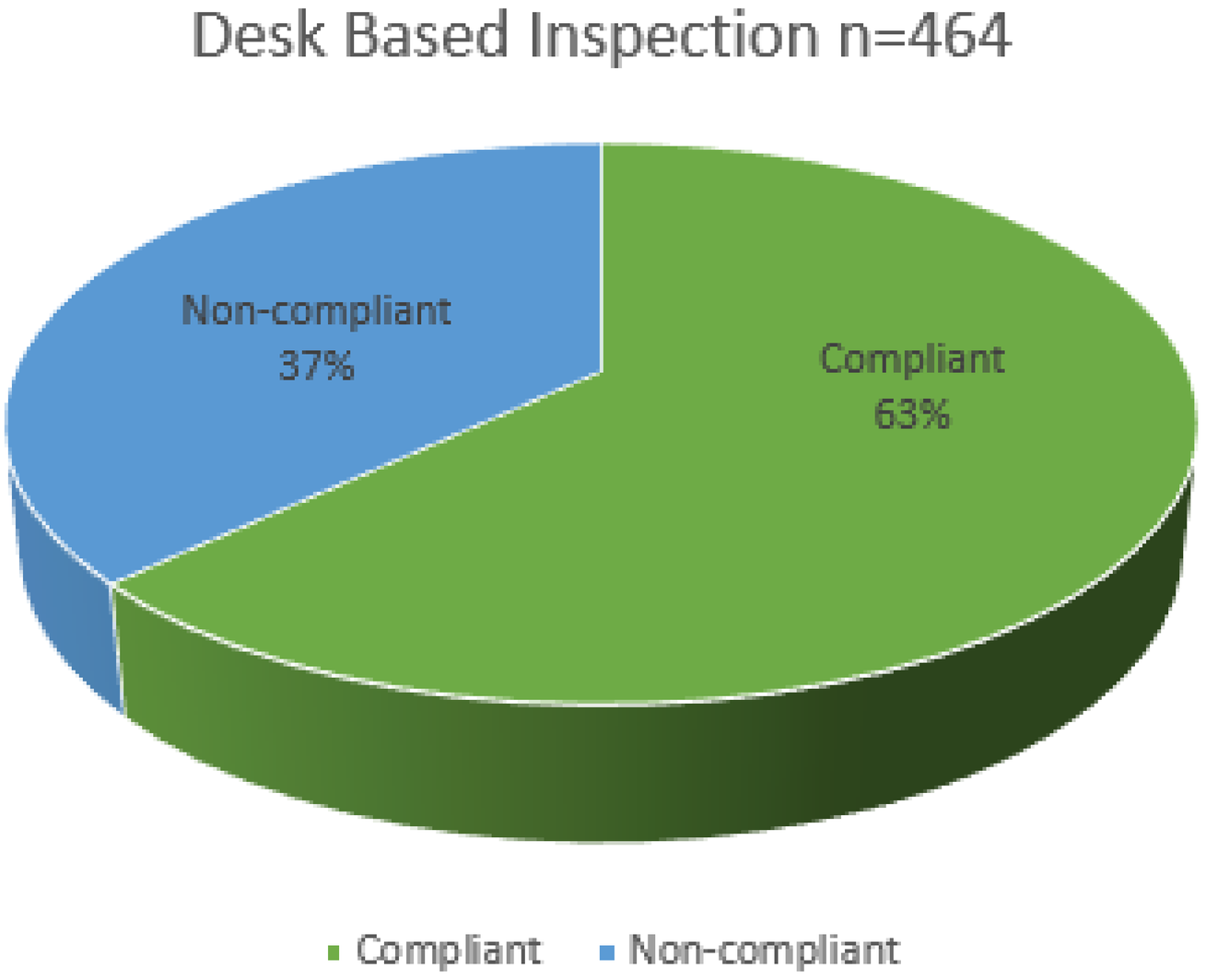
- Product recall from retail/wholesale level, returned to distributor/manufacturer with documentary proof;
- Product subjected to seizure and disposal/destruction as hazardous waste at owner’s expense (proof of disposal/destruction required)
- Compliance notice (action required within specified timeframe)
- Targeted follow-up inspections
- Fixed Penalty Notice

Market Surveillance Findings

Biocide Retail Inspections 2024



Biocide Desk based inspections 2024



Issues identified - 2024

- Labelling non-compliances of registered products
  - No UFI
  - AS name and content different to register
  - Trade name different to label
  - No/limited use instructions
- Revoked products passed sell-out dates (27 stores – notified products and 28 stores authorised products)
- No records of goods in/out for AVKs (PT 14) – (6 stores)
- Not taking measures to ensure PT 14 professional and trained professional products not sold to general public (7 stores)
- Desk based inspection – mostly non-registered product

Biocide Formulation results 2022-2024

Year	No of products	PT 1	Pt 8	PT 14	N.C.
2024	26	0	0	26	2
2023	5	5	0	0	0
2022	39	35	2	3	5

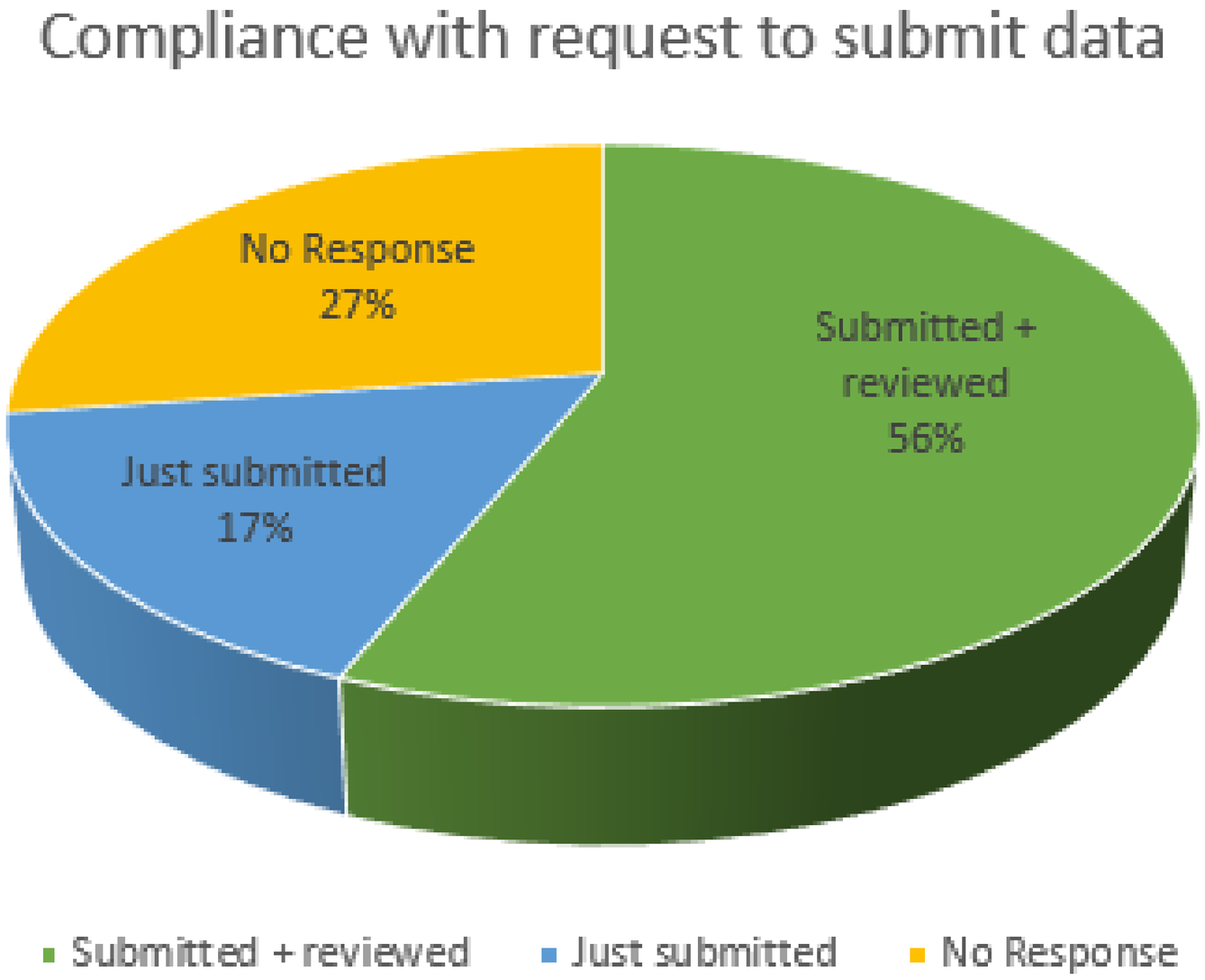
Where a product is found to be out of spec, a follow-up investigation is carried out. This can result in all remaining product of that particular batch being removed from the market.

Biocide End-User Inspections 2024

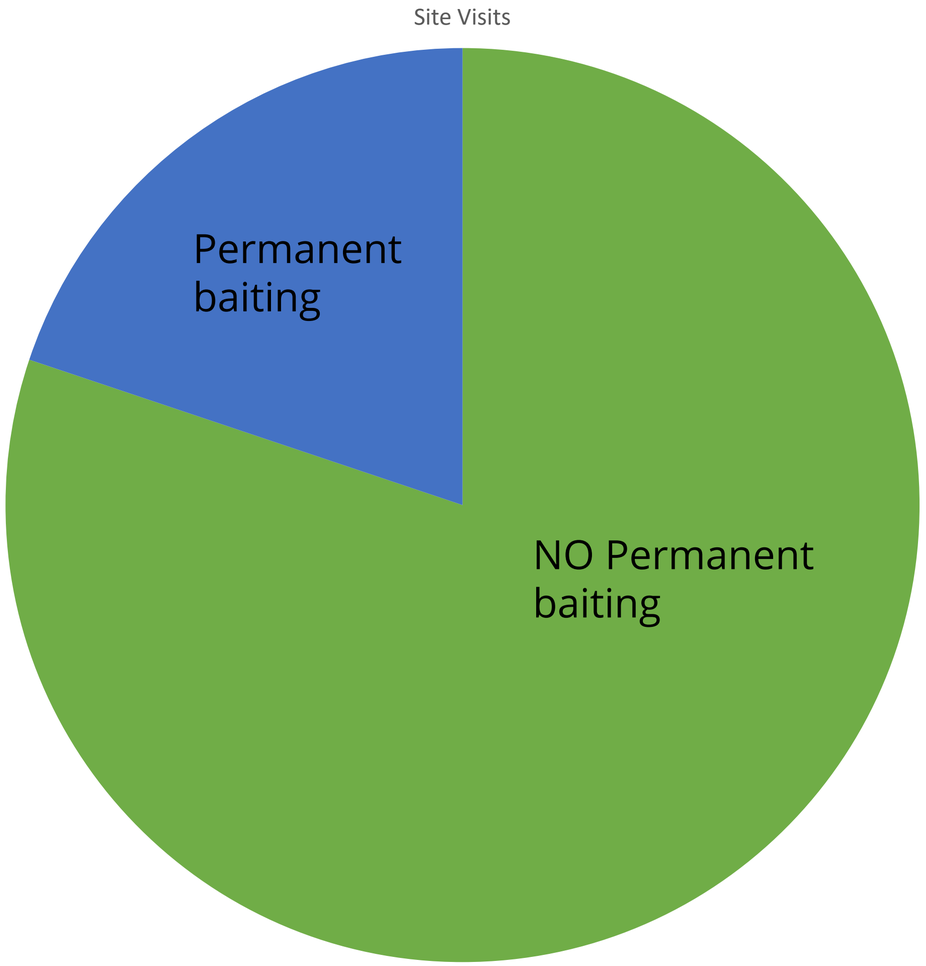
- In-Person inspections – 18 customer sites – records were very poor. Decided to do a targeted desk based audit

- Desk based audit - 50 PMUs (trained professional users of PT 14) randomly selected. 7 retired so selected another 7 to make up 50 active PMU's.
  - Audited the purchase and use of product
  - Questionnaire on use provided – included questions such as do you perform permanent baiting?
  - Records for all customer sites over two days requested
  - Records of purchase of product over a 6 month period

Results of PMU End-User Audit



Results – 21 PMU Responses



- Total Site Visits = **131**
- Average ~7 sites over 2 days / PMU
  - ~3 sites/day/PMU
- Sites with Permanent Baiting = **26**
- **<20%** are permanently baiting
- **Questionnaire – Are you permanent baiting?**
- **7** PMUs - yes
- **9** PMUs - No – records indicate they are permanent baiting on sites
- 1 Major Non-Compliance identified,

  8 occurrences of Brodifacoum used >35 days

Importance of internal audits

Issues identified on Enforcement

- Most issues identified on enforcement should be picked up by regular internal audits by notification/authorisation holders

- Common issues
  - Active Substance (AS) name incorrect – different format to register/review programme
  - Content of AS incorrect
  - Trade name incorrect
  - UFI missing

What sort of checks should be included in internal audits?

- Audits should be carried out every 6-12 months and include the following checks
  - **Name of AS in Review programme**
  - **Status of AS in Review programme**
    - Initial Application for Approval In-Progress
      - “Competent authority evaluation”,
      - “Opinion development by BPC”,
      - “Commission decision”,
    - Approved
    - Approved - Renewal in progress
  - **Does label details match biocides register / SPC (Authorised)**
  - **Does SDS need a re-review**
  - **Any New Regulatory Requirements**

Conclusion

Conclusion

1. Poor compliance with changing requirement (Annex VIII UFI)
2. Details on register and label not aligned
3. Need better internal controls to manage compliance
4. Companies need to engage fully in the process sooner

Thank you for listening

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