CHEMICAL APPROVALS

MEASURE TWICE. CUT ONCE.

Powered by Chemwatch

Your Speakers

Jerome Marinkovic

Director of Product Research & Development, Chemwatch

Jerome is the Director of Product Research & Development at Chemwatch with over 6 years experience in the chemicals management marketplace.

His professional experience in chemical risk assessment includes development and deployment of the Chemwatch control banding risk assessment and approval system.

Jerome has advised many companies and government departments on chemical risk management with a particular focus on risk analysis issues and techniques.

Jerome holds a B Sc degree in Marine Biology and a Graduate Certificate in Software Project Management.

Claude Neri

Head of Compliance and Research Department, Chemwatch

Claude Neri is the Head of Compliance and Research Department at Chemwatch with over 17 years experience in the chemicals management marketplace.

His professional experience as a Chemical Database Project Technical Manager and Chemical Safety Projects Manager includes the successful management of a wide variety of projects such as chemical database web applications, molecular modeling and QSAR techniques. Claude holds BS degrees in Environmental Management of Hazardous Materials and Mathematics and a MS in Analytical Chemistry.

Chemwatch

We are:

- An international company, headquartered in Australia, with offices throughout Europe, the US and Asia-Pacific
- A large employer of science graduate and postgraduates (including chemists, toxicologists and OHS specialists) and IT specialists (over 250 world-wide)
- A successful company with over 25 years of service to the chemicals safety community
- Thousands of clients globally, including hospitals, research institutes, and government departments.

Chemical Approvals

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OVERVIEW

- To compete in a global marketplace and satisfy evolving customer demands, companies are constantly introducing new products containing new chemicals.
- A multi-staged approval system can help organizations to overcome both internal and external challenges of achieving chemical compliance
- Combining external and internal requirements is challenging for any organization.
- In this webinar we will cover how software technology has evolved to become the perfect platform for Chemical Approvals, governed by workflow.

Chemical Approvals

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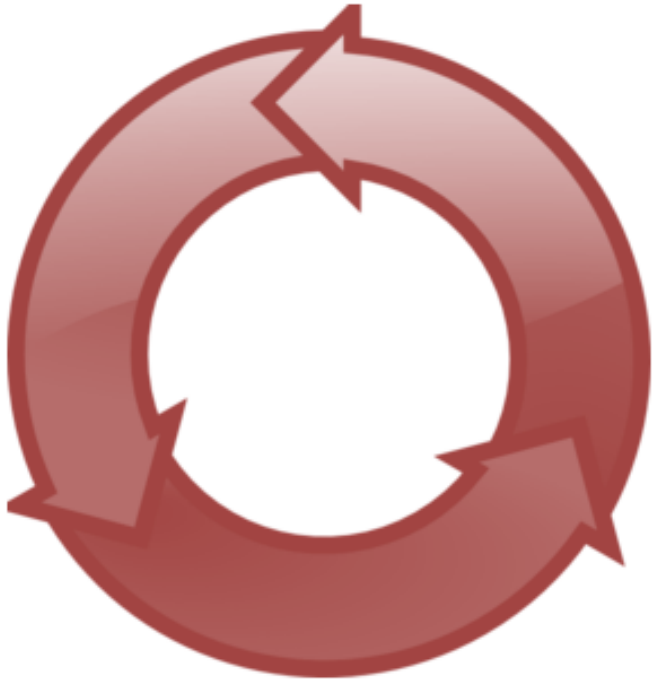
STARTING THE CHEMICALS MANAGEMENT CYCLE

- The chemicals management cycle starts with the evaluation of products and substances.

- An effective system will provide an integrated approach to chemical approvals, bringing together:
  - Environmental, Health and Safety review
  - Regulatory, Supply Chain and Product Management objectives
  - Organizational Structures, Business Processes and Procedures

In summary, approvals are

- driven by clear objectives, and
- governed by regulations, policies and procedures



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THE STORY

ELV regulation in the EU(2000/53/EC).
Article 4 2(a) states
2. (a) Member States shall ensure that materials and components of vehicles put on the market after 1 July 2003 do not contain lead, mercury, cadmium or hexavalent chromium **other than in cases** listed in **Annex II** under the conditions specified therein;

6. Vibration dampers		X
7(a). Vulcanising agents and stabilisers for elastomers in fluid handling and powertrain applications containing up to 0,5 % lead by weight	1 July 2006	
7(b). Bonding agents for elastomers in powertrain applications containing up to 0,5 % lead by weight		
8. Solder in electronic circuit boards and other electric applications		X (i)
9. Copper in friction materials of brake linings containing more than 0,4 % lead by weight	1 July 2007	X
10. Valve seats	Engine types developed before 1 July 2003: 1 July 2007	
11. Electrical components which contain lead in a glass or ceramic matrix compound except glass in bulbs and glaze of spark plugs		X (ii) (for components other than piezo in engines)

Annex II of this regulation offers exemptions to materials to be used in particular applications.

Hazard Classification

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BASELINE CRITERIA

Classification of chemicals is a "dark art".
Vendors differ amongst themselves, often, drawing upon similar evidence.
As an example, the EU publishes a database of Classifications called the C&L Inventory (not to be confused with CLP)
Around **120,000** substances has been Classified by close to **4 million** notifiers.
Some substances are represented by more than **30 different "opinions"**
Some mixtures built from these substances may therefore represent **100's of opinions.**

Hazard Classification

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BASELINE CRITERIA

Where any one substance is produced by two companies, the level of disagreement on the classification of hazard/risk is greater than 50%!

An irritant is an irritant, a toxin is a toxin and a burn is just that. A chemical exhibits the same properties and hazards no matter who supplies it. There should be no grey zone or subjective guess. It's not like picking the richest, aromatic coffee grounds.

	Sigma	Merck	Acros	Fisher	Alfa
Sigma	-	58% (1720/2960)	57% (1798/3165)	58% (3308/5745)	54% (5137/9520)
Merck	58% (1720/2960)	-	61% (565/933)	61% (1148/1890)	63% (1818/2897)
Acros	57% (1798/3165)	61% (565/933)	-	57% (61/107)	56% (1601/2848)
Fisher	58% (3308/5745)	61% (1148/1890)	57% (61/107)	-	60% (3018/5014)
Alfa	54% (5137/9520)	63% (1818/2897)	56% (1601/2848)	60% (3018/5014)	-

Chemical Approval Criteria

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Review Type	Resources / Information	Actions
REGULATORY	Up to date SDS Vendor Ingredient Disclosure Up to date Regulatory Databases Classified Chemical Families	Check each Ingredient against **lists of concern** Ensure Chemical Families are Covered Ensure Alerts when Regulatory status changes
WORKPLACE HEALTH AND SAFETY	Standards and Codes of Practice Safe Use Instructions (SUI) Hazard Assessments (MINI SDS) Risk Assessments Signage and Labeling advice Personal Protection Reports Standard Operating Procedures (SOPs) First Aid and Fire Fighting Reports Spills and Disposal Reports	**Place the Chemical into the workplace** Assess potential impacts to Workers health and safety Follow Codes of Practice and Standards Ensure appropriate Personal Protection is available Assess Health, Physical risks Ensure Clear Safe Use Instructions are available Ensure First Aid and Emergency information is available Ensure Spills can be contained and managed Ensure Disposal management covers the chemical
GLOBAL HEALTH AND SAFETY	Toxicological Reports Expert Review SDS (Peer review) Health Surveillance Requirements Biological Monitoring Requirements Limited Evidence - Latest Research	**Expert review of potential impacts to the wellbeing of workers and public** Consideration of limited evidence Take into account new research
ENVIRONMENTAL	Environmental Reports Reporting Tools (Seveso, SARA,...)	**Expert review of environmental Risks** Ensuring all the Reporting Requirements will be met Internal Reporting - e.g. Corporate Responsibility, Insurance External Reporting - as required by governing bodies
BUSINESS and OPERATIONAL	Forms Attachments Supply Chain implications Distribution Financial	Capture as much information from the REQUESTOR Communicate relevant information, documents and attachments Consider operational aspects and potential implications Distribution and Supply Chain review Financial Review

“Forming” the Approval

TRADITIONALLY, FORMS FORM FORMS

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FORM A

REQUEST QUESTIONNAIRE

FORM B

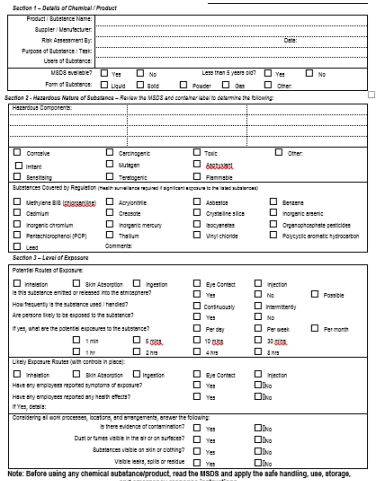
CHEMICAL REVIEW QUESTIONNAIRE

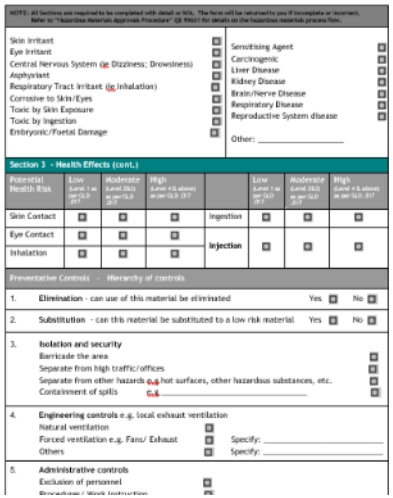
FORM C

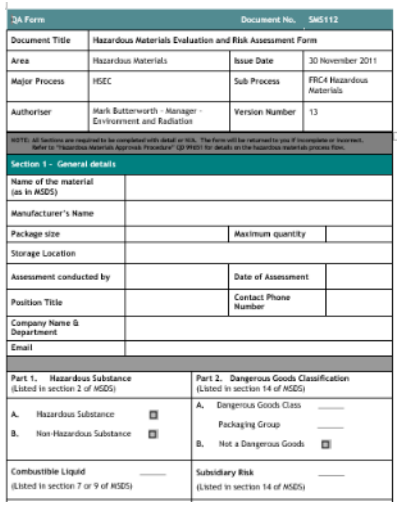
WORKPLACE REVIEW QUESTIONNAIRE

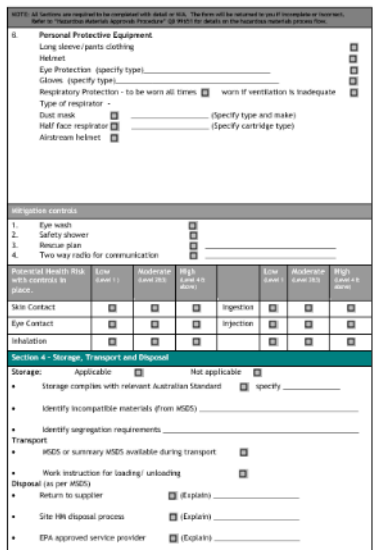
FORM D

SIGN OFF QUESTIONNAIRE









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Building an Approvals System

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APPROVALS SYSTEM BUILDING BLOCKS

BUILDING BLOCK	FRAMEWORK	SOLUTION
FORMS	Requests, Comments, Checklists and Attachments.	From initial Request to the final Approval, all the necessary information is captured as required by the Organization. Each Stakeholder is forced to provide mandatory information to progress the request to the next stage.
SDS Data & Documents	SDS Management Data Extraction Formulation capture	SDS is the key component of the entire approvals process. This engine drives the Vendor SDS management, Data Extraction, and Formulation capture.
REGULATIONS	Regulatory comparison, alerts and **Red Flag automation**	The key stage of the approvals journey is to ensure that each substance is checked against relevant Regulatory lists.
REPORTS	Reports, Documents, Tables required during review	With Form and SDS Data captured in a Database, the ***reports component*** can calculate, extract and present any combination of data points, or documents, to relevant stakeholders.
ALERTS	High Impact information presented at the right time, to the right stakeholders.	Alerting relevant stakeholders of new and pending requests.
WORKFLOWS	Automation of the Approval Review process. Distributing the relevant information, forms and actions to the right stakeholders.	Creating an Approvals Workflow framework that automates the entire approval process.
ESCALATION	Date, Duration or Special Criteria can drive escalation	Automated escalation based on any criteria captured in the system.
DASHBOARDS	Business Intelligence.	Immediate and up to date view of all requests, approval history, and stakeholder activity.

Forms

APPROVALS SYSTEM BUILDING BLOCKS

Forms are essential to any Approval System.

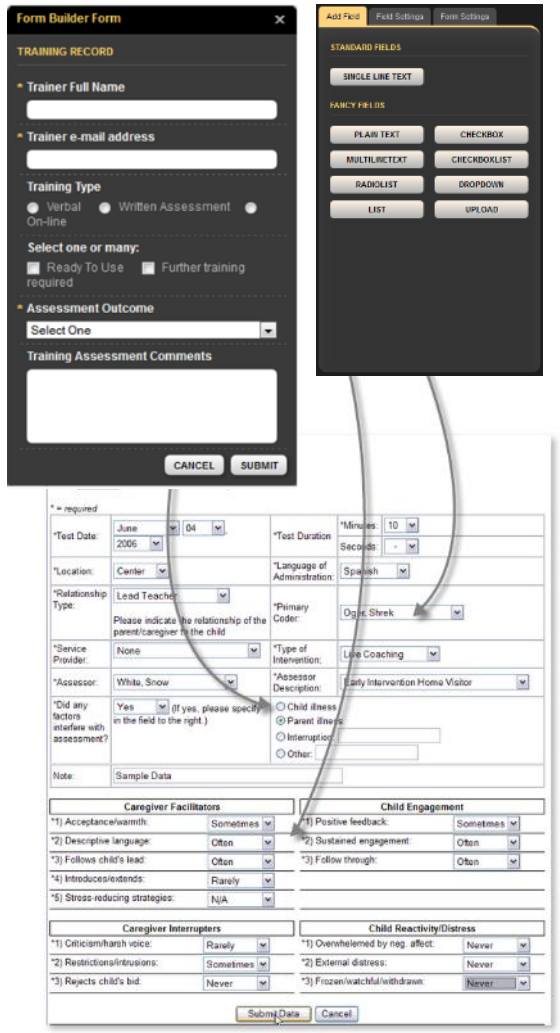
Any form can be created using the combination of:

- Plain Input Text fields
- Multi-line text fields
- Checkbox fields and menus
- Radio-button fields and menus
- Drop down menus
- Date pickers
- Upload buttons
- Lists

Multiple forms can be assigned to one or many Stakeholders, at any stage of the Approval Process.

Data captured using Forms can be used to:

- Generate Reports and Documents
- Direct the Workflow
- Trigger Alerts and Notifications
- Search the database
- etc.



SDS Data & Documents

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APPROVALS SYSTEM BUILDING BLOCKS

SDS holds the information fundamental to Chemical Approval processes.

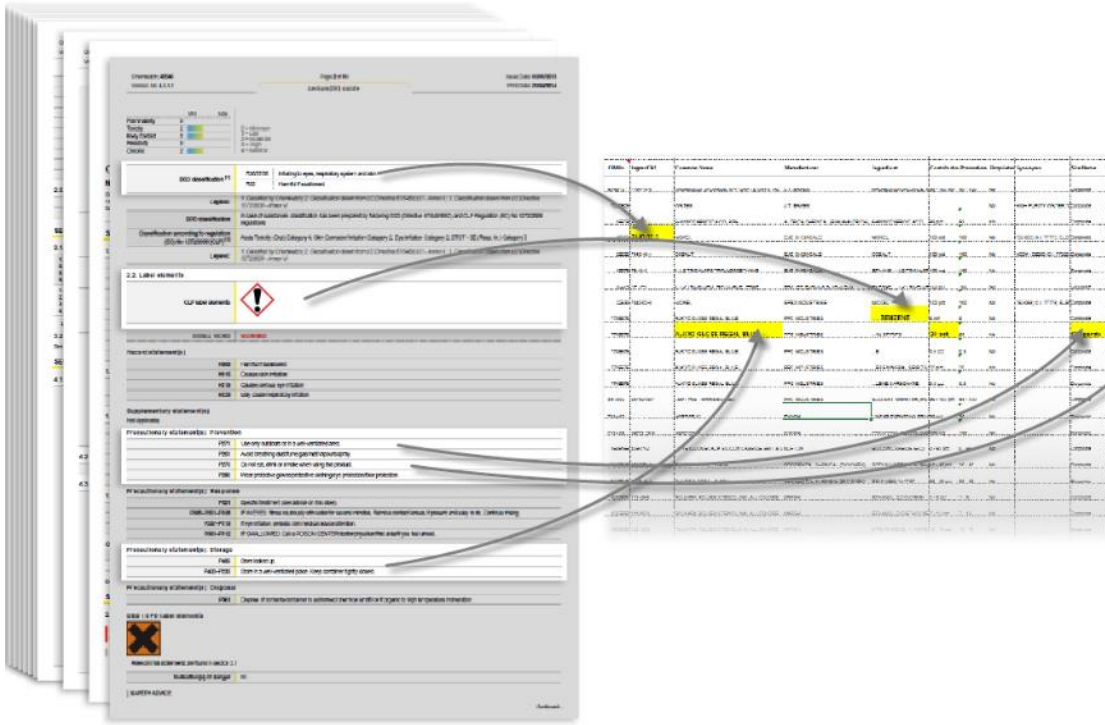
Typically, the SDS is acquired from the supplier of a chemical. Several Data Points from the SDS are of particular interest:

- Ingredient formulation
- Physical Properties
- Transport Information (DG data)
- Hazard Analysis

Based on the above information, an extensive approval review can be done by tapping into:

- Regulatory databases
- Classification rules
- Transport Databases
- Internal Databases

A system will allow these checks to be automated thus streamlining and simplifying the approval process.



Regulations

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APPROVALS SYSTEM BUILDING BLOCKS

One of the most critical parts of the approval process is ensuring you comply with local regulations.

This will generally require the use of a regulatory database.

Depending on the nature of the business, you may require reference to national and global regulations as well.

Having access to a regulatory database has the following advantages:

- Will likely contain regulations outside of your local jurisdiction
- Regulatory data is ‘deciduous’ - it changes often and requires constant maintenance
- Many regulations make reference to chemical ‘families’ or groups. Importance of proper indexing so that you capture all regulations pertaining to a substance.
- Regulations come in all shapes and sizes and need to be normalized so that they can be easily searched using various identifiers (CAS, EC, TSCA No., etc.).

Reports

APPROVALS SYSTEM BUILDING BLOCKS

Combining the information captured from:

- Forms
- SDS
- Regulations
- Any other available data

Reports building block can generate documents and reports such as:

- Environmental Reports
- Standard Operating Procedures
- Personal Protection Summaries
- Toxicological Reports
- Regulatory Reports

Each Report can be set as one of the key resources to review, requiring sign off, and approval.

Alerts Engine

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APPROVALS SYSTEM BUILDING BLOCKS

Systemised approach to Approvals eliminates short cuts.

Even in a pre-defined workflow, special conditions or situations warrant special responses.

These situations can be:

- Delays in processing
- Significant regulatory concerns (external)
- Internal HSE concerns (High Risk chemicals)
- Financial/Business Risks (Vendor Risk, etc.)

Special conditions can trigger automatic alerts or notifications.

In a time where information overload is considered “normal”, *alerts* mechanism can greatly improve user adoption of an Approvals system.

Facebook, Twitter, and most widely adopted applications utilise notifications and alerts to add “importance” to some content over other.

Workflow

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APPROVALS SYSTEM BUILDING BLOCKS

It is the very Brain of the operation!

Workflows govern, direct and combines all components of an approvals system.

It Directs:

- Approval Stages
- Action sequences
- Transitions between stages

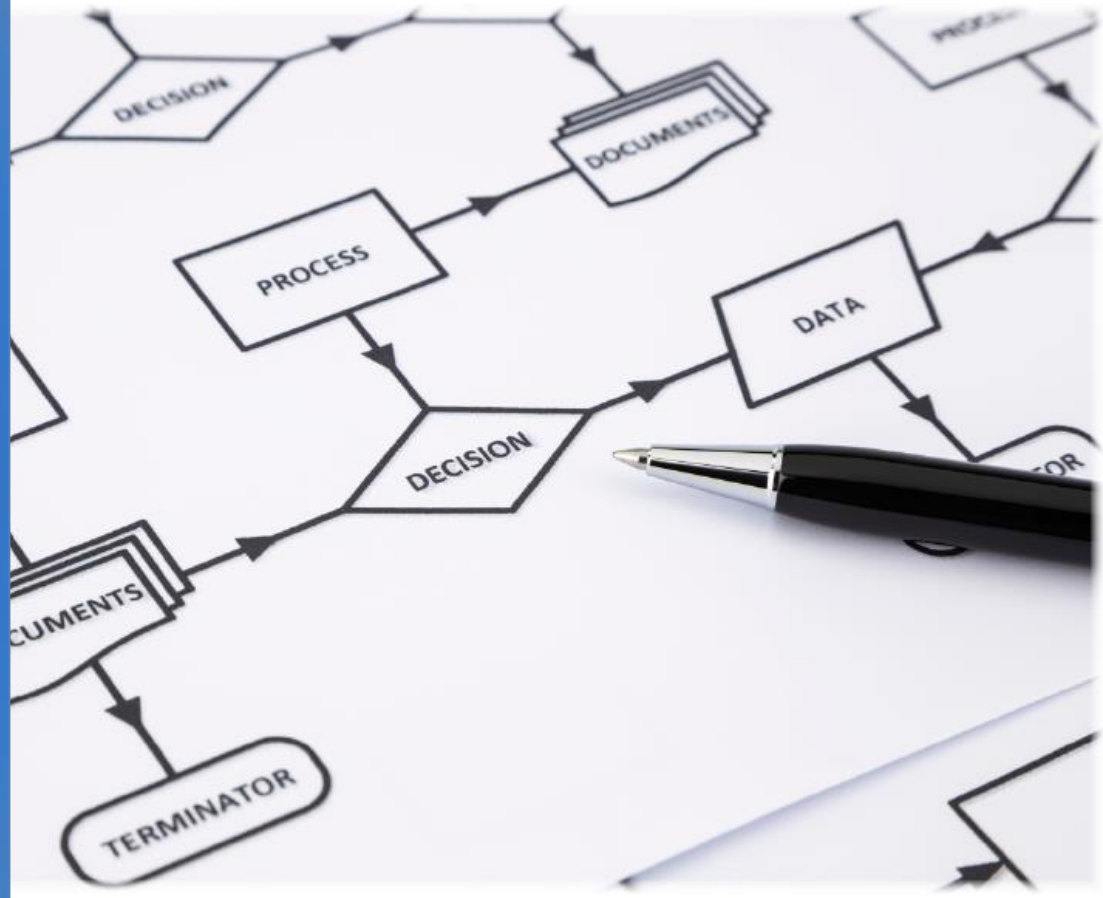
It Governs:

- Approval Rules and Regulations
- Stakeholder tasks and actions

It Combines:

- Forms, documents and reports
- Actions and action streams

Workflows can provide the tools and functionality to translate any *Process* into a systemised stream of tasks, actions and alerts.



Dashboards

APPROVALS SYSTEM BUILDING BLOCKS

Providing intelligence:

Perhaps best summarised by Peter F Drucker:

"What's measured improves"

Systemisation of any process can greatly improve the efficiency of the operation.

With an immediate access to:

- Summaries of all approval requests
- Durations of review
- Breakdown by stage, task or action
- Number of new requests over time
- Number of resolved requests over time

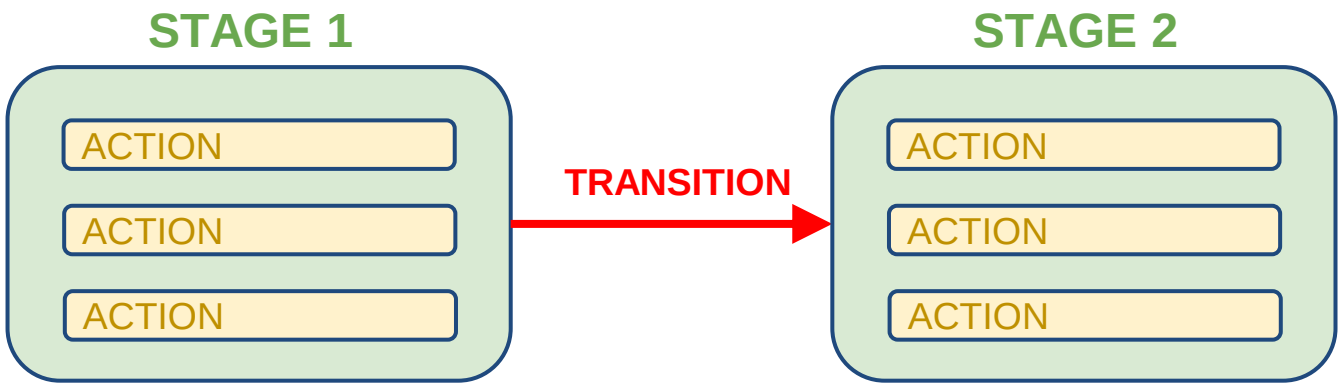
The administrator will have in-depth knowledge of how the approval system is used.

"If it can be measured, it can be Managed"

Peter F. Drucker, an Austrian-born American management consultant, educator, and author, whose writings contributed to the philosophical and practical foundations of the modern business corporation.

Approvals Workflow

THE BASICS

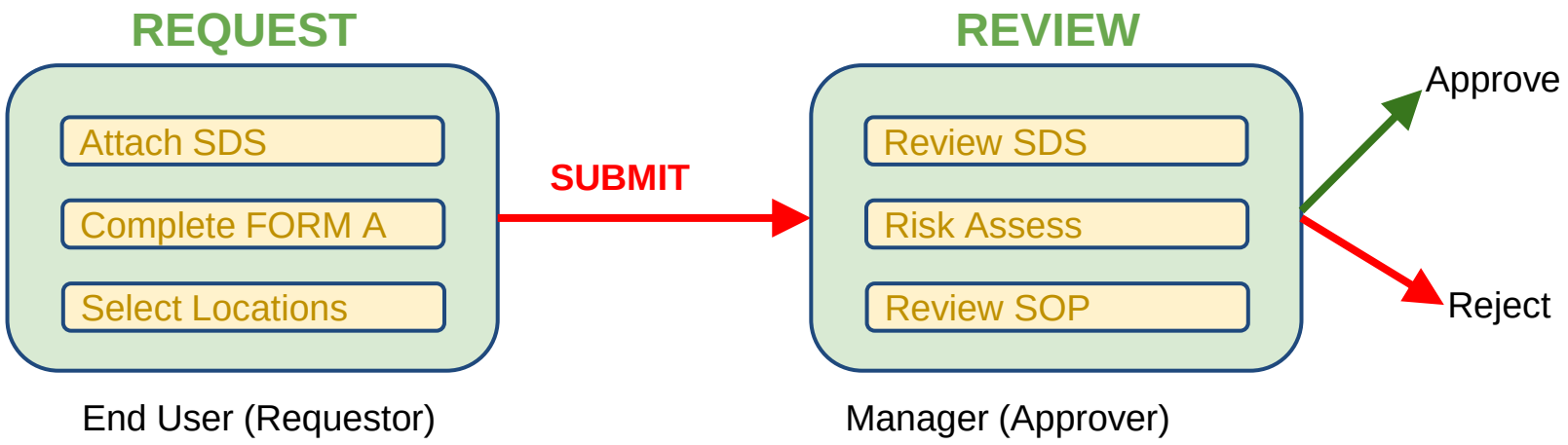


Approvals Workflow can be broken down into few simple components:

- **STAGE** (e.g. Request Stage, Local Approval Stage, Environmental Review Stage, etc.)
- **ACTION** (e.g. Extract SDS data, Fill Form, Complete Risk Assessment, etc.)
- **TRANSITION** (e.g. Send back to Requestor, Approve, Reject, or Criteria Based.)

Approvals Workflow

THE BASICS



- Each STAGE has an OWNER.
- OWNER is the Stakeholder responsible for a particular Approval aspect.
- In larger organisations (multi national) Stakeholders are usually governed by User-groups.

- In the following slides we will cover several real life approval workflow scenarios.

Approvals Workflow

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A REAL LIFE EXAMPLE

To bring together all the “building blocks” covered in todays presentation, we have prepared an example of an approval process comprised of 4 stages.

There is no limit to the number of Workflow scenarios that can be achieved with this approach.

REQUEST | LOCAL REVIEW | ENVIRONMENTAL | HEALTH & SAFETY

Approvals Workflow

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TYPICAL SCENARIO

REQUEST | **LOCAL** | **ENVIRONMENTAL** | **HEALTH & SAFETY**

Approval Process begins with the REQUEST STAGE

Approvals Workflow

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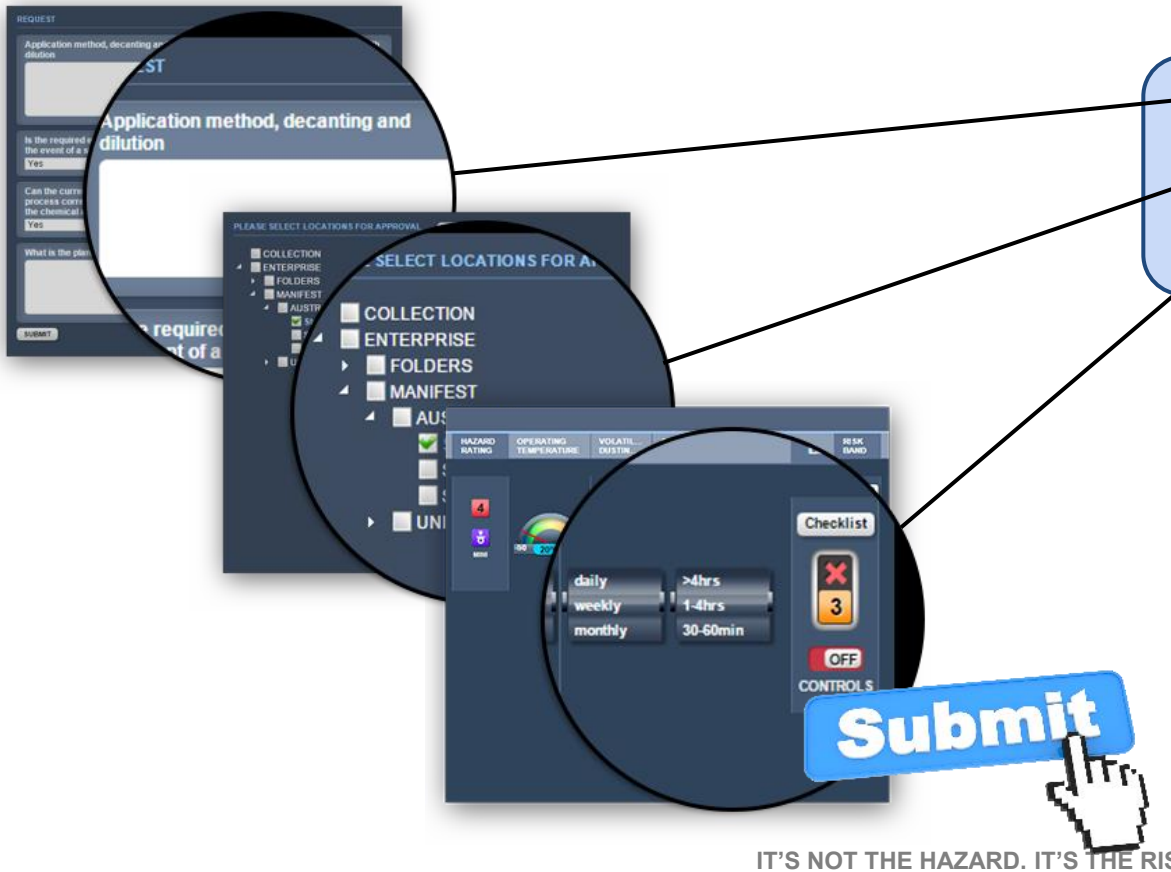
TYPICAL SCENARIO

REQUEST | LOCAL | ENVIRONMENTAL | HEALTH & SAFETY

Approval Process begins with the REQUEST STAGE



ACTIONS

- Fill Request Form
- Select Location(s)
- Specify Task Scenario (Risk Assess)

IT'S NOT THE HAZARD. IT'S THE RISK

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Approvals Workflow

TYPICAL SCENARIO

REQUEST | **LOCAL** | ENVIRONMENTAL | HEALTH & SAFETY

Local Approval Stage "places" the Chemical into the Workplace

Approvals Workflow

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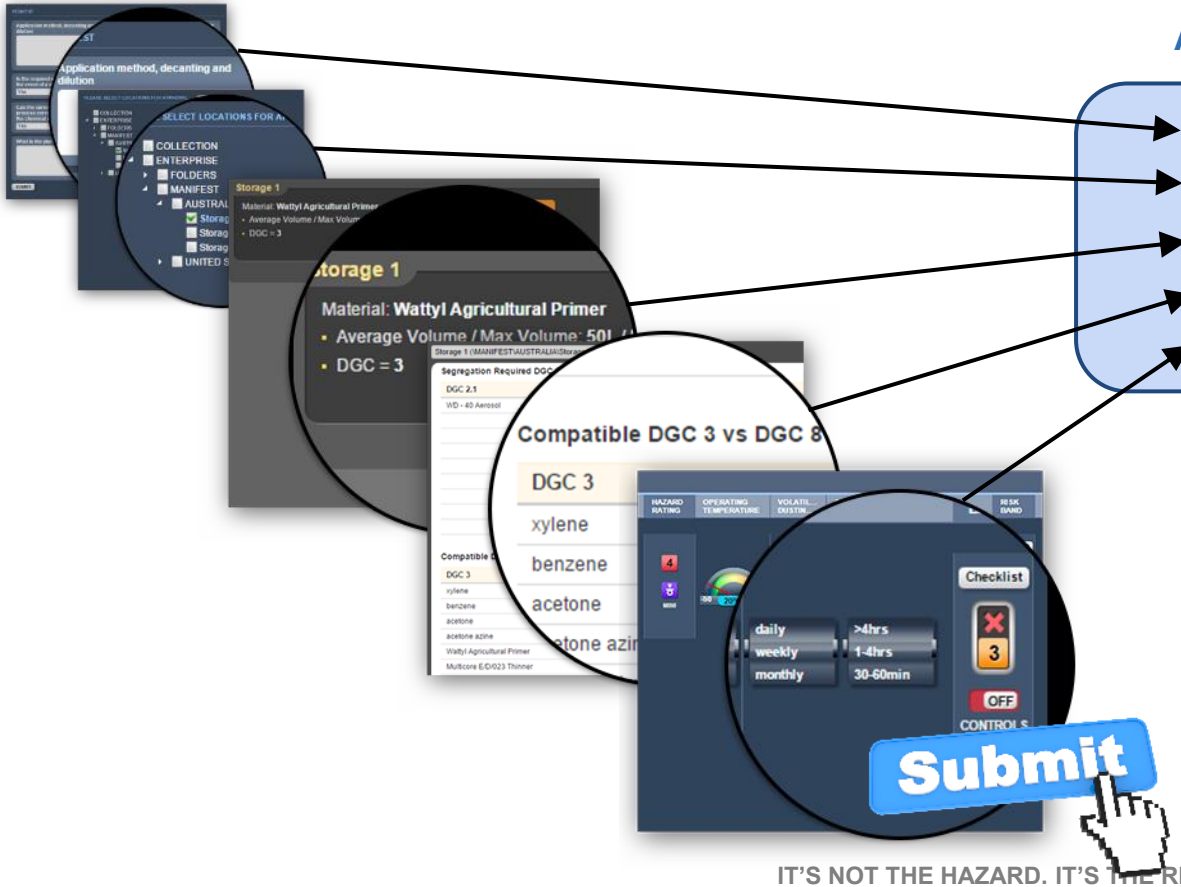
TYPICAL SCENARIO

REQUEST | **LOCAL** | ENVIRONMENTAL | HEALTH & SAFETY

Local Approval Stage "places" the Chemical into the Workplace



ACTIONS

- Review Request Form
- Review Locations Selected
- Review Storage Requirements
- Review Incompatibilities
- Complete Risk Assessment

IT'S NOT THE HAZARD. IT'S THE RISK

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Approvals Workflow

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TYPICAL SCENARIO

REQUEST | LOCAL | **ENVIRONMENTAL** | HEALTH & SAFETY

Environmental Review looks at potential risks and concerns related to Environmental Impacts

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Approvals Workflow

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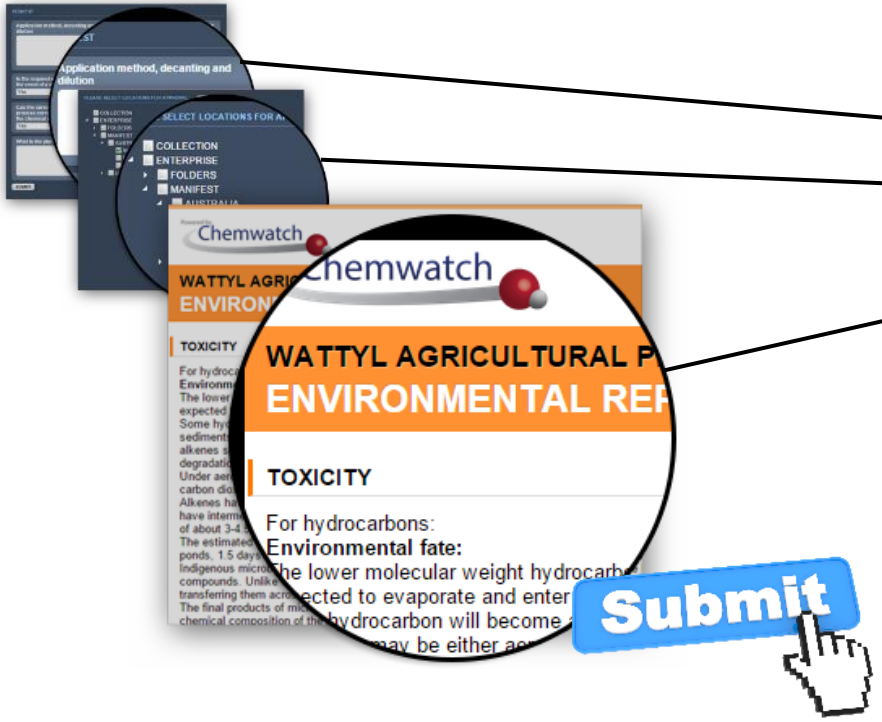
TYPICAL SCENARIO

REQUEST | LOCAL | **ENVIRONMENTAL** | HEALTH & SAFETY

Environmental Review looks at potential risks and concerns related to Environmental Impacts



ACTIONS

- Review Request Form
- Review Locations Selected
- Review Environmental Report

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Approvals Workflow

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TYPICAL SCENARIO

REQUEST | LOCAL | ENVIRONMENTAL | **HEALTH & SAFETY**

HSE Review looks at global concerns related to the storage, use and distribution of the Chemical

Approvals Workflow

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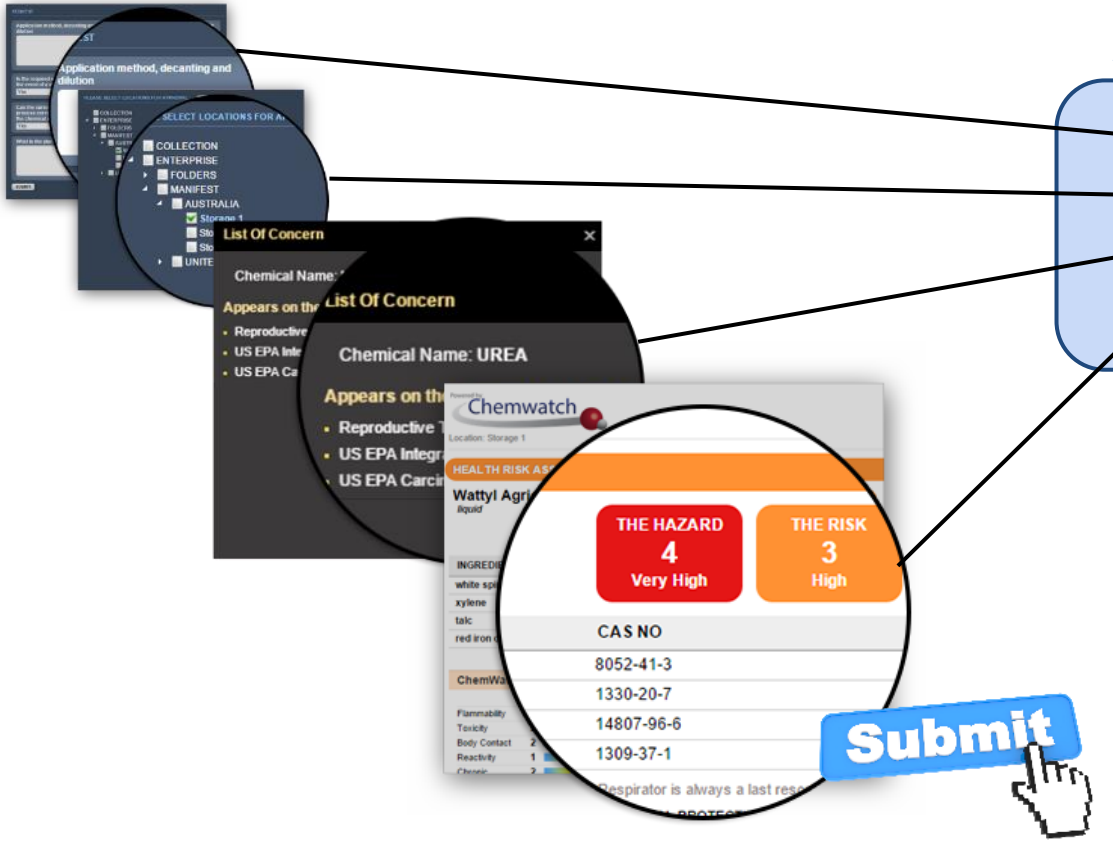
TYPICAL SCENARIO

REQUEST | LOCAL | ENVIRONMENTAL | **HEALTH & SAFETY**

HSE Review looks at global concerns related to the storage, use and distribution of the Chemical



ACTIONS

- Review Request Form
- Review Locations Selected
- Review Regulatory Concerns
- In Depth Hazard & Risk Analysis

IT'S NOT THE HAZARD. IT'S THE RISK

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Approvals Workflow

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CONDITIONAL WORKFLOW

REQUEST | LOCAL | ENVIRONMENTAL | **HIGH BUSINESS RISK** | HEALTH & SAFETY

RED FLAGGED Chemicals can trigger special stages requiring expert review

Rules can used to automatically **Flag** chemicals of concern

Rules can apply to Classification, Regulation or any other data point of interest

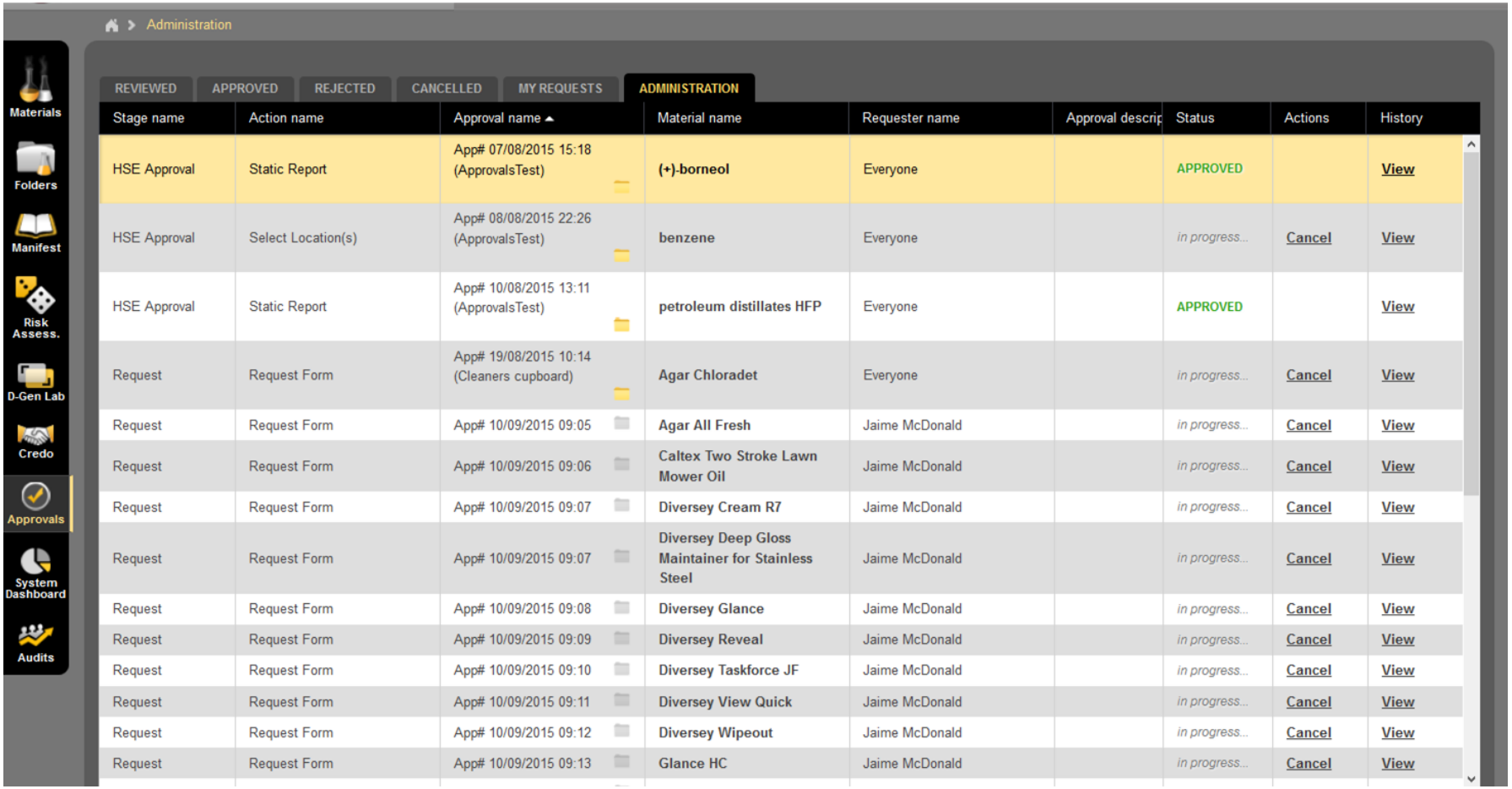
These Rules can be used to trigger special stages or actions relevant to the organisation

EXAMPLE RULE

IF
{ the *Product* contains a **PROP 65** listed *Substance* }
THEN
{ Apply Red Flag }
&
{ Trigger Stage 3A Approval Review }

Approvals Administration

BUSINESS INTELLIGENCE MATTERS



Stage name	Action name	Approval name	Material name	Requester name	Approval descrip	Status	Actions	History
HSE Approval	Static Report	App# 07/08/2015 15:18 (ApprovalsTest)	(+)-borneol	Everyone		APPROVED		View
HSE Approval	Select Location(s)	App# 08/08/2015 22:26 (ApprovalsTest)	benzene	Everyone		in progress...	Cancel	View
HSE Approval	Static Report	App# 10/08/2015 13:11 (ApprovalsTest)	petroleum distillates HFP	Everyone		APPROVED		View
Request	Request Form	App# 19/08/2015 10:14 (Cleaners cupboard)	Agar Chloradet	Everyone		in progress...	Cancel	View
Request	Request Form	App# 10/09/2015 09:05	Agar All Fresh	Jaime McDonald		in progress...	Cancel	View
Request	Request Form	App# 10/09/2015 09:06	Caltex Two Stroke Lawn Mower Oil	Jaime McDonald		in progress...	Cancel	View
Request	Request Form	App# 10/09/2015 09:07	Diversey Cream R7	Jaime McDonald		in progress...	Cancel	View
Request	Request Form	App# 10/09/2015 09:07	Diversey Deep Gloss Maintainer for Stainless Steel	Jaime McDonald		in progress...	Cancel	View
Request	Request Form	App# 10/09/2015 09:08	Diversey Glance	Jaime McDonald		in progress...	Cancel	View
Request	Request Form	App# 10/09/2015 09:09	Diversey Reveal	Jaime McDonald		in progress...	Cancel	View
Request	Request Form	App# 10/09/2015 09:10	Diversey Taskforce JF	Jaime McDonald		in progress...	Cancel	View
Request	Request Form	App# 10/09/2015 09:11	Diversey View Quick	Jaime McDonald		in progress...	Cancel	View
Request	Request Form	App# 10/09/2015 09:12	Diversey Wipeout	Jaime McDonald		in progress...	Cancel	View
Request	Request Form	App# 10/09/2015 09:13	Glance HC	Jaime McDonald		in progress...	Cancel	View

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