

# **Risk Management**

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Risk can be defined as the combination of the probability of an event and its consequences (ISO/IEC Guide 73).

Risk management should be a continuous and developing process which runs throughout the organisation's strategy and the implementation of that strategy.

It must translate the strategy into tactical and operational objectives, assigning responsibility throughout the organisation with each manager and employee responsible for the management of risk as part of their job description

The focus of good risk management is the identification and treatment of these risks. Its objective is to add maximum sustainable value to all the activities of the organisation.

# **A Risk Management Standard**

Published by AIRMIC, ALARM, IRM: 2002

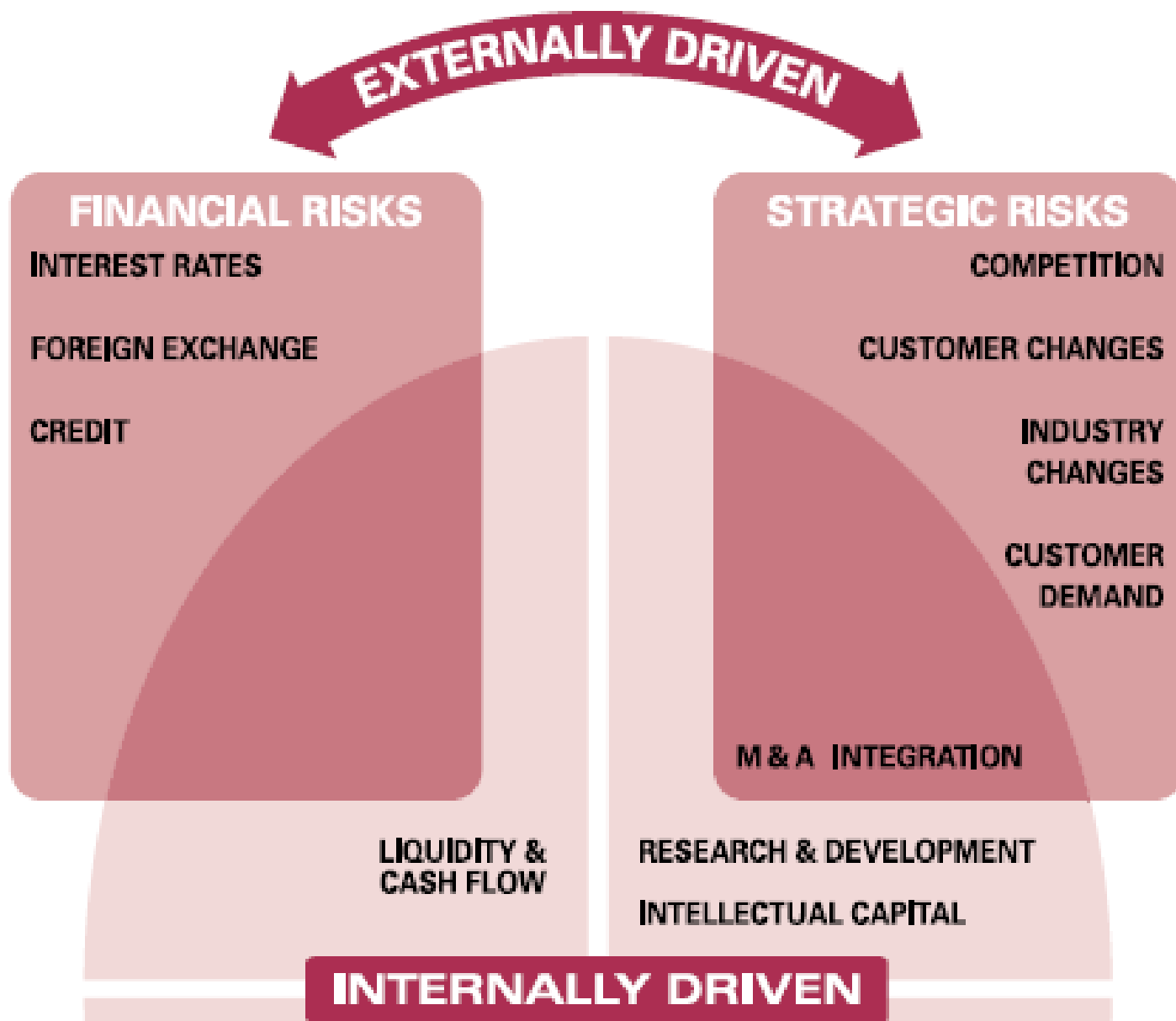
**ALARM The National Forum for  
Risk Management in the Public Sector**

[www.alarm-uk.com](http://www.alarm-uk.com)

**The Association of  
Insurance and Risk Managers**

[www.airmic.com](http://www.airmic.com)

# Drivers of Key Risks



# INTERNALLY DRIVEN

ACCOUNTING CONTROLS

INFORMATION SYSTEMS

RECRUITMENT

SUPPLY CHAIN

REGULATIONS

CULTURE

BOARD  
COMPOSITION

OPERATIONAL RISKS

PUBLIC ACCESS

EMPLOYEES

PROPERTIES

PRODUCTS &  
SERVICES

CONTRACTS

NATURAL  
EVENTS

SUPPLIERS

ENVIRONMENT

HAZARD RISKS

EXTERNALLY DRIVEN

# Framework for Enterprise Risk Management

©



Risk Types	Examples
Strategic	<ul style="list-style-type: none"> <li>■ Reduction in business vitality (due to change in business strategy, customer spending patterns, product discovery &amp; development, changing technology, etc.)</li> <li>■ Loss of intellectual property &amp; trade secrets</li> <li>■ Competition for talent</li> <li>■ Negative impact to reputation/loss of trustmark</li> </ul>
Operational	<ul style="list-style-type: none"> <li>■ Disruption to product supply</li> <li>■ Counterfeiting</li> <li>■ Inefficient use of resources/increased product cost</li> <li>■ Physical property/damage/disruption</li> <li>■ Discontinuation of global data flows</li> </ul>
Compliance	<p>Violation of laws or regulations governing areas such as:</p> <ul style="list-style-type: none"> <li>■ Environmental</li> <li>■ Employee health &amp; safety</li> <li>■ Clinical trial subject/patient safety</li> <li>■ Product quality/safety issues (violations of FDA and other Health Authority regulations, Pharmacovigilance)</li> <li>■ Selling and promotion of our products (including Health Care Compliance (HCC), Foreign Corrupt Practices Act (FCPA)/global Anti-Corruption laws, U.S. government contracts/programs)</li> <li>■ Protection of personal data in accordance with global data protection requirements</li> <li>■ Local tax and statutory laws</li> </ul>
Financial & Reporting	<ul style="list-style-type: none"> <li>■ Currency exchange, funding &amp; cash flow, credit risk</li> <li>■ Financial misstatement (including violation of the Sarbanes Oxley Act)</li> </ul>

Select Risk Management Functions	Strategic Risk	Operational Risk	Compliance Risk	Financial & Reporting Risk
Corporate Internal Audit			X	X
Environment, Health & Safety		X	X	
Global Finance	X		X	X
Global Medical Organization			X	
Global Security	X	X	X	
IT Risk Management (ITRM)	X	X	X	X
J&J Health Care Compliance & Privacy			X	
J&J Human Resources- Talent Mgt	X			
J&J Law Department	X		X	
J&J Quality & Compliance		X	X	
J&J Supply Chain	X	X	X	



## **Risk Types J&J**

### **Strategic**

customer spending patterns, product discovery & development, changing technology, etc.)

Loss of intellectual property & trade secrets

Competition for talent

Negative impact to reputation/loss of trustmark

### **Operational**

Disruption to product supply

Counterfeiting

Inefficient use of resources/increased product cost

Physical property/damage/disruption

Discontinuation of global data flows

## **Compliance**

Violation of laws:

Environmental

Employee health & safety

Product quality/safety

Selling and promotion

Anti-Corruption laws, U.S. government contracts/programs)

Protection of personal data in accordance with global data protection

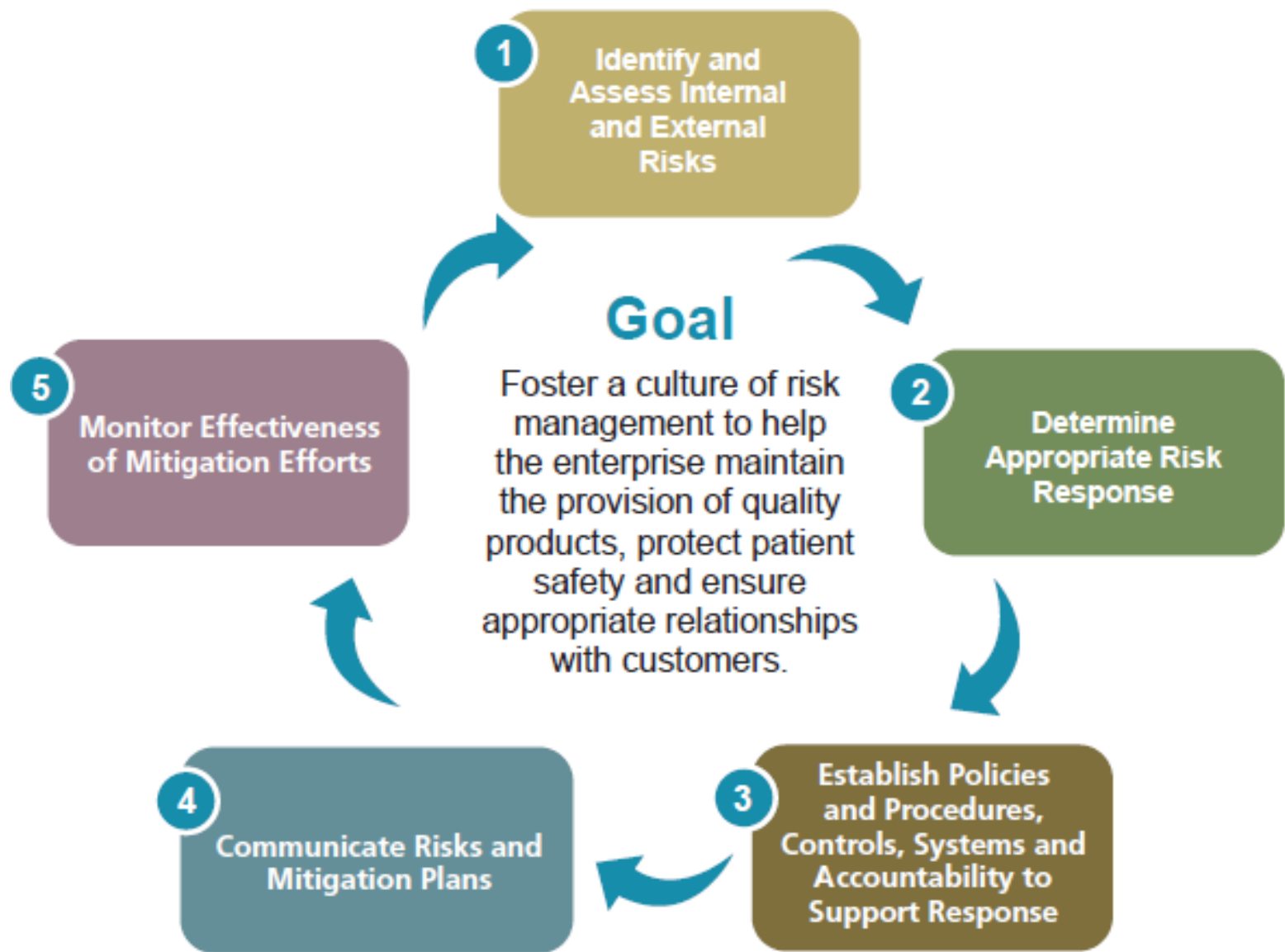
requirements

Local tax and statutory laws

## **Financial & Reporting**

Currency exchange, funding & cash flow, credit risk

Financial misstatement (including violation of the Sarbanes Oxley Act)



**2013**

**World Investment and Political Risk**

World Investment Trends and Corporate  
Perspectives

The Political Risk Insurance Industry  
Breach of Contract

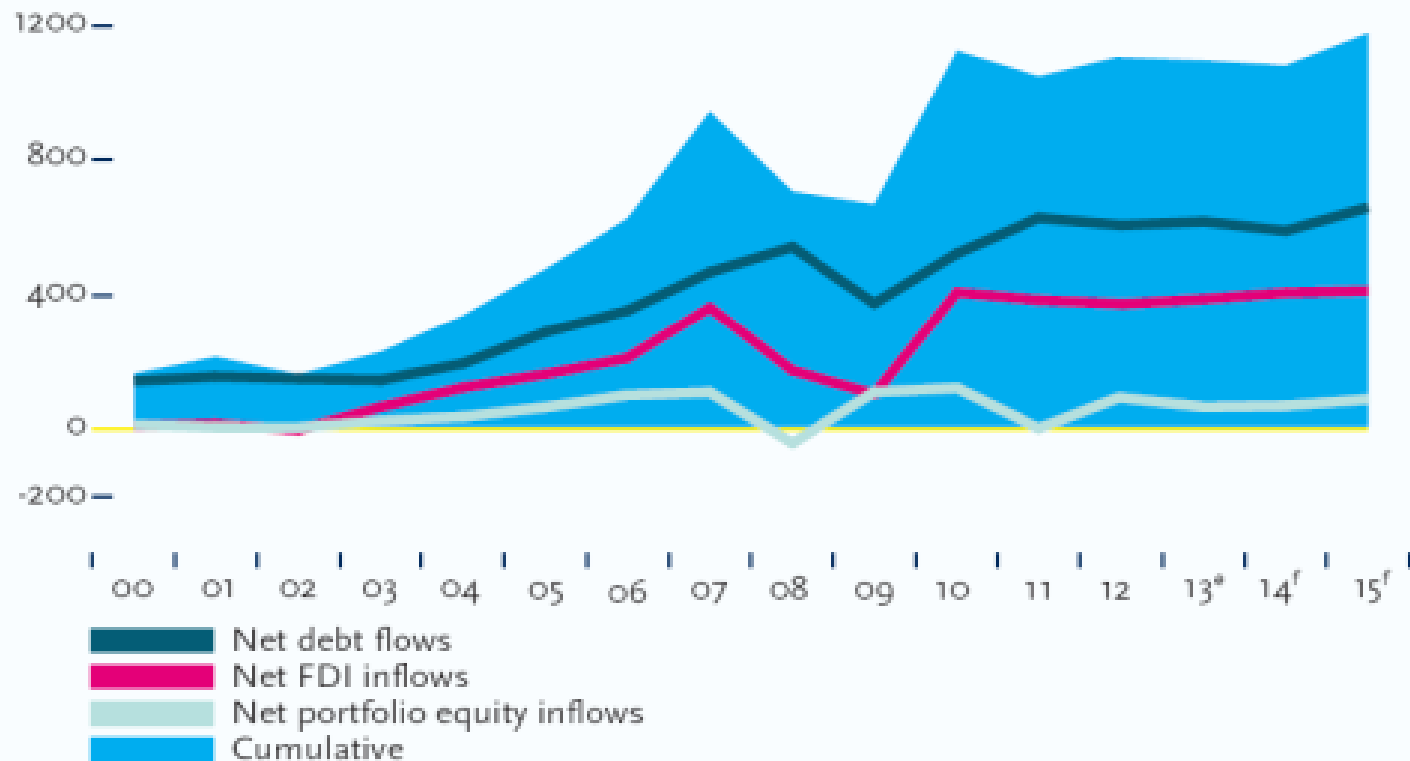
**TABLE 1**  
**MAJOR CONSTRAINTS TO FOREIGN INVESTMENT**  
**OVER THE NEXT THREE YEARS**  
*percent*

	2010	2011	2012	2013
<b>Number of respondents</b>	<b>94</b>	<b>316</b>	<b>438</b>	<b>459</b>
Limited size of the market	9	7	7	5
Lack of investment opportunities	7	-	-	-
Poor infrastructure	9	11	8	7
Lack of qualified staff	10	17	18	18
Lack of financing for investments in these countries	5	11	13	13
Political risk	21	18	22	19
Macroeconomic instability	16	15	20	21
Lack of information on the country's business environment	2	-	-	-
Weak government institutions/red tape/corruption	19	13	8	10
Other	2	2	1	1
Increased government regulation in the aftermath of the global financial crisis	-	5	3	4

*Source: MIGA-EIU annual political risk surveys*

**FIGURE 1.1**  
NET PRIVATE CAPITAL FLOWS TO DEVELOPING ECONOMIES

\$ billion

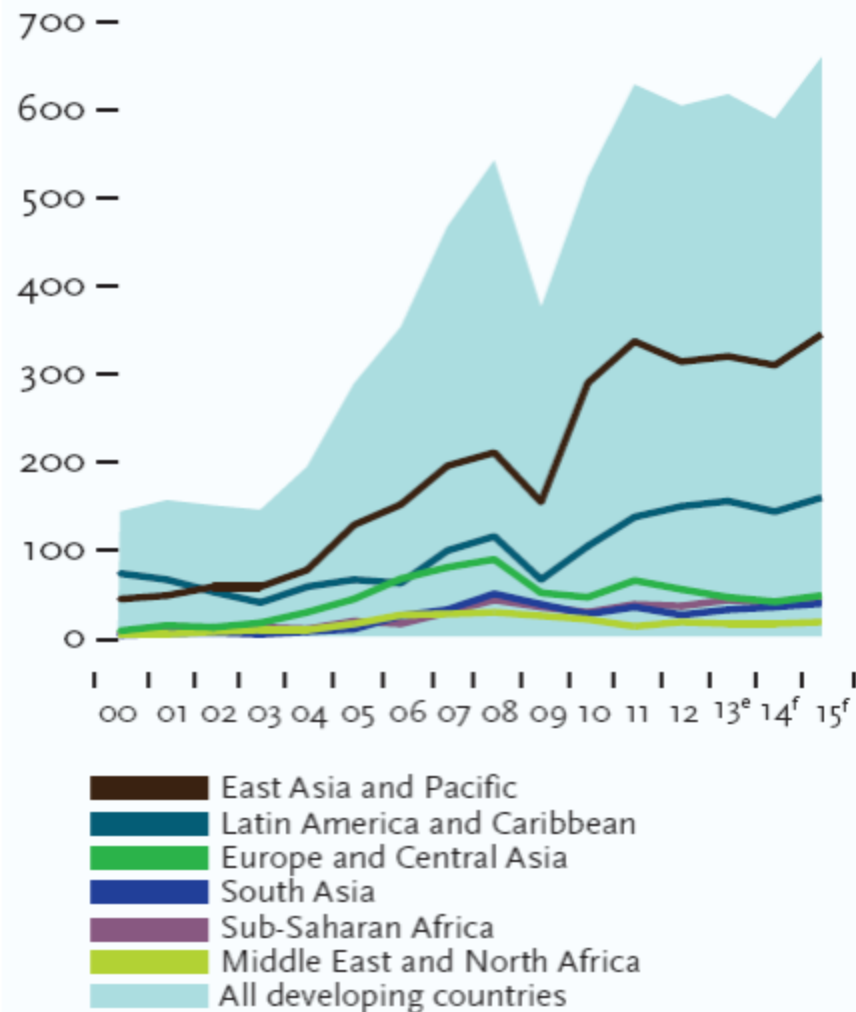


Source: World Bank  
e= estimate; f= forecast

### FIGURE 1.3

## FDI FLOWS TO DEVELOPING ECONOMIES BY REGION

\$ billion



Source: World Bank

**TABLE 1.2**  
**REGIONAL FDI**

REGION	2013 <sup>e</sup> REPORT CARD
East Asia and Pacific	↑2%
South Asia	↑21%
Europe and Central Asia	↓16%
Latin America and Caribbean	↑4%
Middle East and North Africa	↓15%
Sub-Saharan Africa	↑19%

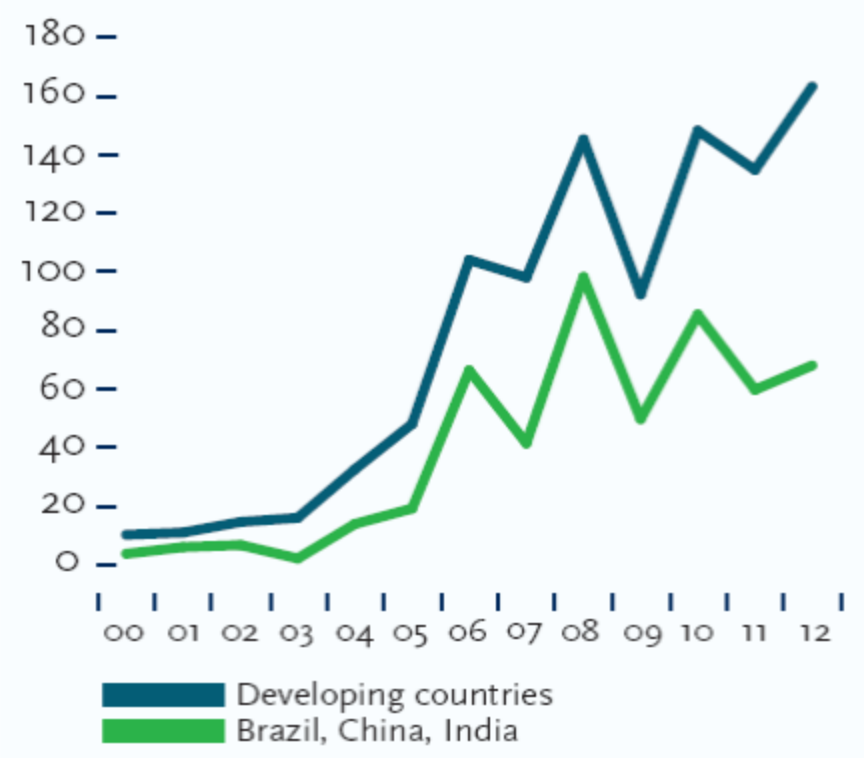
*Source: World Bank*

*e= estimate*



**FIGURE 1.4**  
**FDI FLOWS FROM DEVELOPING ECONOMIES**

*\$ billion*

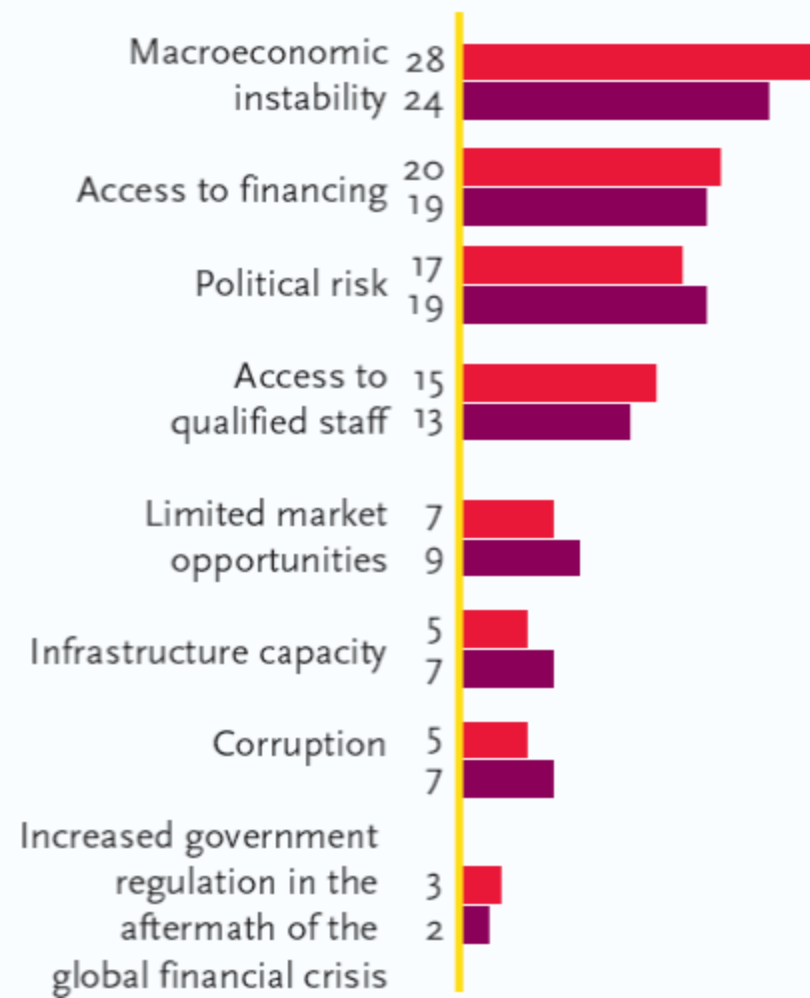


*Source: World Bank*

**FIGURE 1.6**

**RANKING OF THE MOST IMPORTANT  
CONSTRAINTS TO FDI IN DEVELOPING  
ECONOMIES FOR SOUTH-BASED  
INVESTORS**

*percent*



## The Risk Management Process



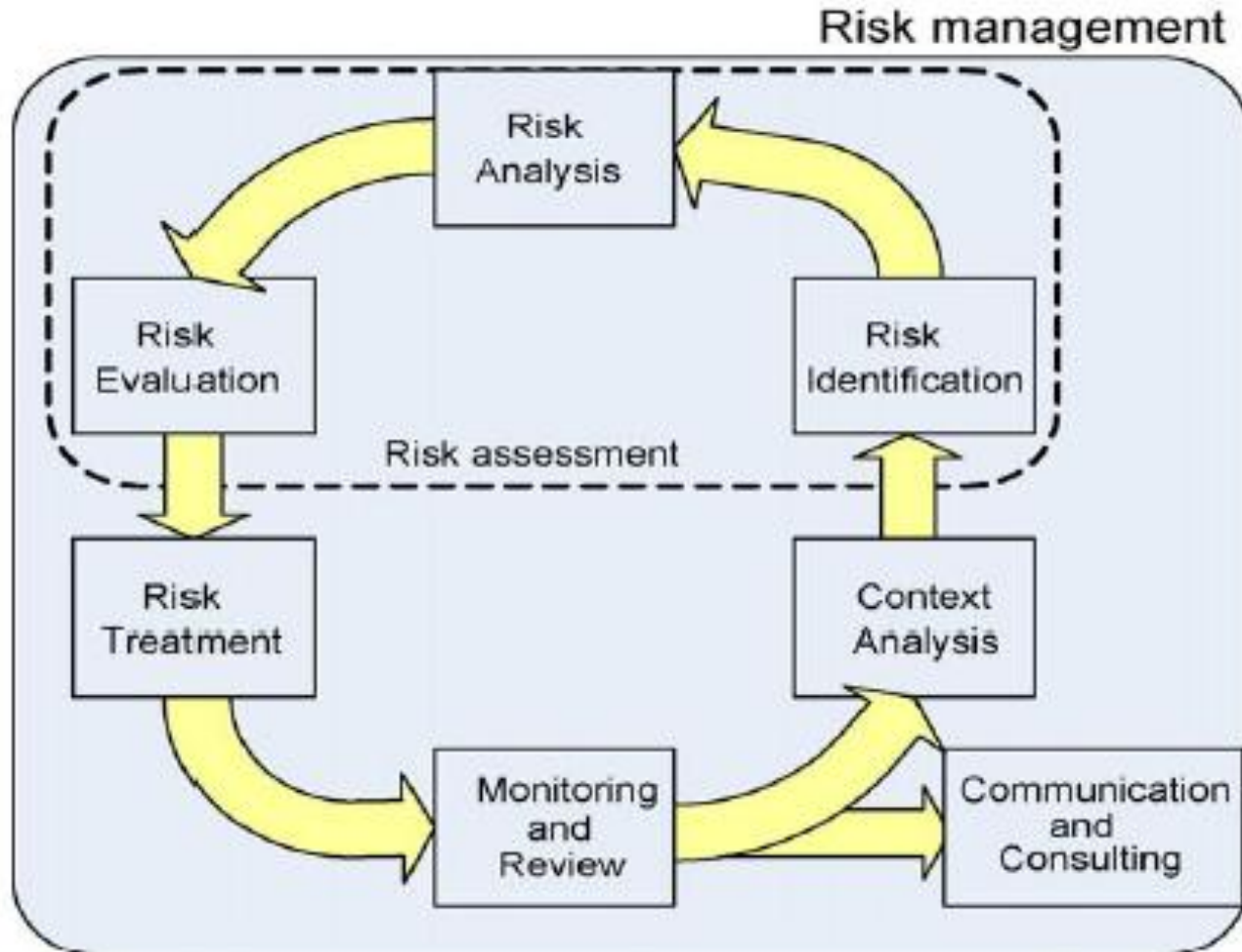


Figure 1: Stages of effective risk management

# **Risk Analysis**

## **Risk Identification**

Methodical way to ensure that all significant activities within the organisation have been identified and all the risks flowing from these activities defined.

# Risk Description

1. Name of Risk	
2. Scope of Risk	Qualitative description of the events, their size, type, number and dependencies
3. Nature of Risk	Eg. strategic, operational, financial, knowledge or compliance
4. Stakeholders	Stakeholders and their expectations
5. Quantification of Risk	Significance and Probability
6. Risk Tolerance/ Appetite	Loss potential and financial impact of risk Value at risk Probability and size of potential losses/gains Objective(s) for control of the risk and desired level of performance
7. Risk Treatment & Control Mechanisms	Primary means by which the risk is currently managed Levels of confidence in existing control Identification of protocols for monitoring and review
8. Potential Action for Improvement	Recommendations to reduce risk
9. Strategy and Policy Developments	Identification of function responsible for developing strategy and policy

# Risk Estimation

## Consequences - Both Threats and Opportunities

High	<p>Financial impact on the organisation is likely to exceed £x</p> <p>Significant impact on the organisation's strategy or operational activities</p> <p>Significant stakeholder concern</p>
Medium	<p>Financial impact on the organisation likely to be between £x and £y</p> <p>Moderate impact on the organisation's strategy or operational activities</p> <p>Moderate stakeholder concern</p>
Low	<p>Financial impact on the organisation likely to be less than £y</p> <p>Low impact on the organisation's strategy or operational activities</p> <p>Low stakeholder concern</p>

## Probability of Occurrence - Threats

Estimation	Description	Indicators
High (Probable)	Likely to occur each year or more than 25% chance of occurrence.	Potential of it occurring several times within the time period (for example - ten years). Has occurred recently.
Medium (Possible)	Likely to occur in a ten year time period or less than 25% chance of occurrence.	Could occur more than once within the time period (for example - ten years). Could be difficult to control due to some external influences. Is there a history of occurrence?
Low (Remote)	Not likely to occur in a ten year period or less than 2% chance of occurrence.	Has not occurred. Unlikely to occur.



## Probability of Occurrence - Opportunities

Estimation	Description	Indicators
High (Probable)	Favourable outcome is likely to be achieved in one year or better than 75% chance of occurrence.	Clear opportunity which can be relied on with reasonable certainty, to be achieved in the short term based on current management processes.
Medium (Possible)	Reasonable prospects of favourable results in one year of 25% to 75% chance of occurrence.	Opportunities which may be achievable but which require careful management. Opportunities which may arise over and above the plan.
Low (Remote)	Some chance of favourable outcome in the medium term or less than 25% chance of occurrence.	Possible opportunity which has yet to be fully investigated by management. Opportunity for which the likelihood of success is low on the basis of management resources currently being applied.

# **Risk Analysis Methods and Techniques**

## **Upside risk**

- Market survey
- Prospecting
- Test marketing
- Research and Development
- Business impact analysis

## **Both**

- Dependency modelling
- SWOT analysis (Strengths, Weaknesses, Opportunities, Threats)
- Event tree analysis
- Business continuity planning
- BPEST (Business, Political, Economic, Social, Technological)
- Decision taking under conditions of risk and uncertainty
- Statistical inference

## **Downside risk**

- Threat analysis
- Fault tree analysis

Causes, weaknesses, proposed design, reliability or safety, human errors, contributors to failure, quantify the failure probability and contributors,

- FMEA (Failure Mode & Effect Analysis)

applicable in Design of Products, Processes and Services.

Taking action to prevent a failure, improve a design control through testing or evaluation, or a process control through inspection.

# **Risk Evaluation**

## **Risk Reporting and Communication**

### ***Internal Reporting***

The Board of Directors

Business Units

Individuals

### ***External Reporting***

report to its stakeholders in community affairs,  
human rights,  
employment practices, health and safety and the  
environment

# Risk Treatment

Risk treatment is the process of selecting and implementing measures to modify the risk.

Risk control/mitigation,, risk avoidance, risk transfer, risk financing.

# Monitoring and Review

Regular audits of policy and standards compliance should be carried out and standards performance reviewed to identify opportunities for improvement

## Who, What, When and How

### Level

Product

Project

Activities

### Parameters

Cost

Time

Performance

## **Enterprise Risk Management (ERM)**

Ensure prompt resolution of internally identified risk to compliance with laws and regulations to maintain the provision of quality products, protect patient safety and ensure appropriate relationships with customers



Global risk management survey,  
eighth edition  
Setting a higher bar  
**Financial**

Figure 4. Which of the following risk oversight activities does your company's board of directors or board risk committee(s) perform?

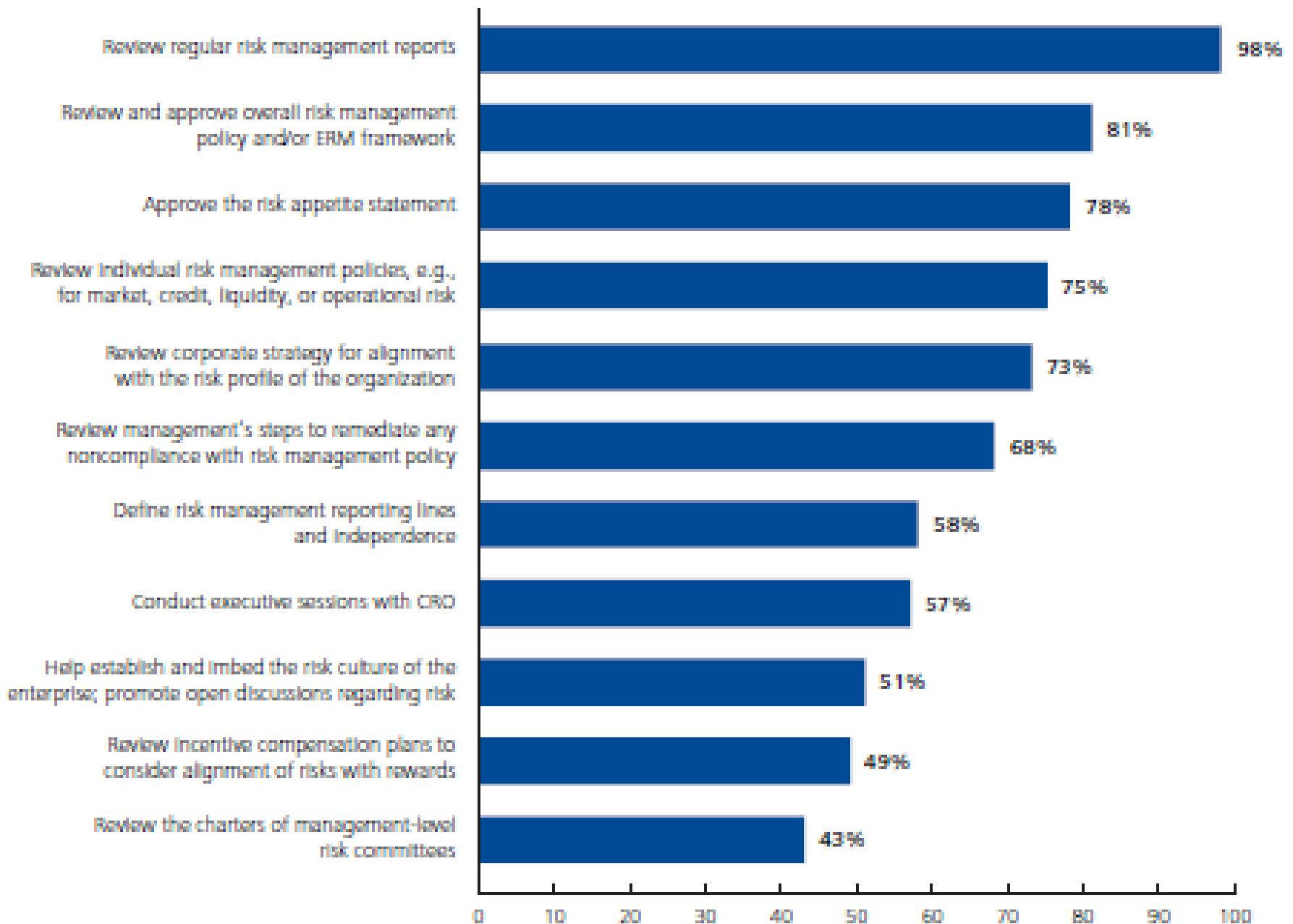


Figure 5. Which risk management considerations does your company incorporate into its incentive plans for senior management personnel?

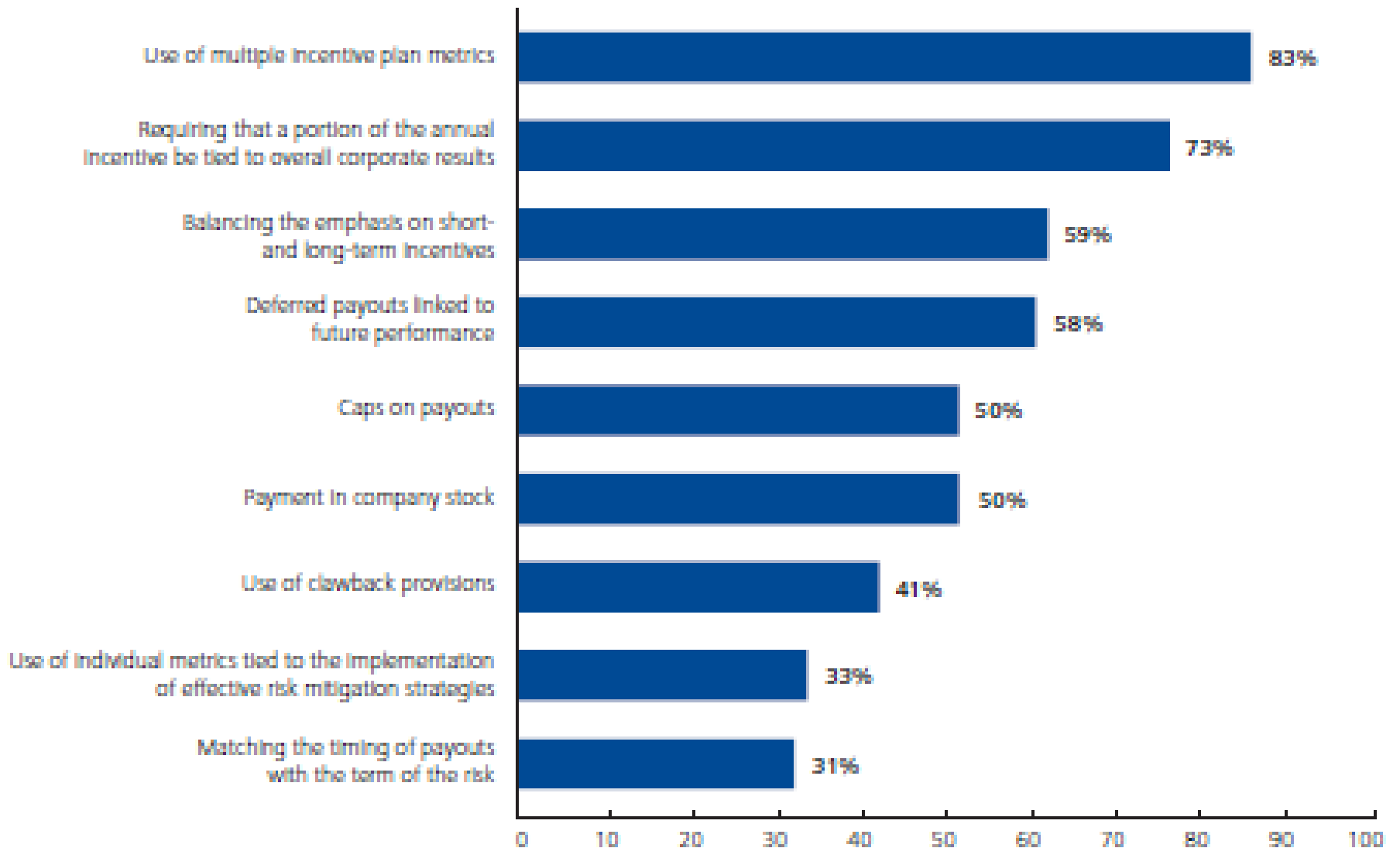


Figure 7. Does your organization have an ERM program or equivalent?

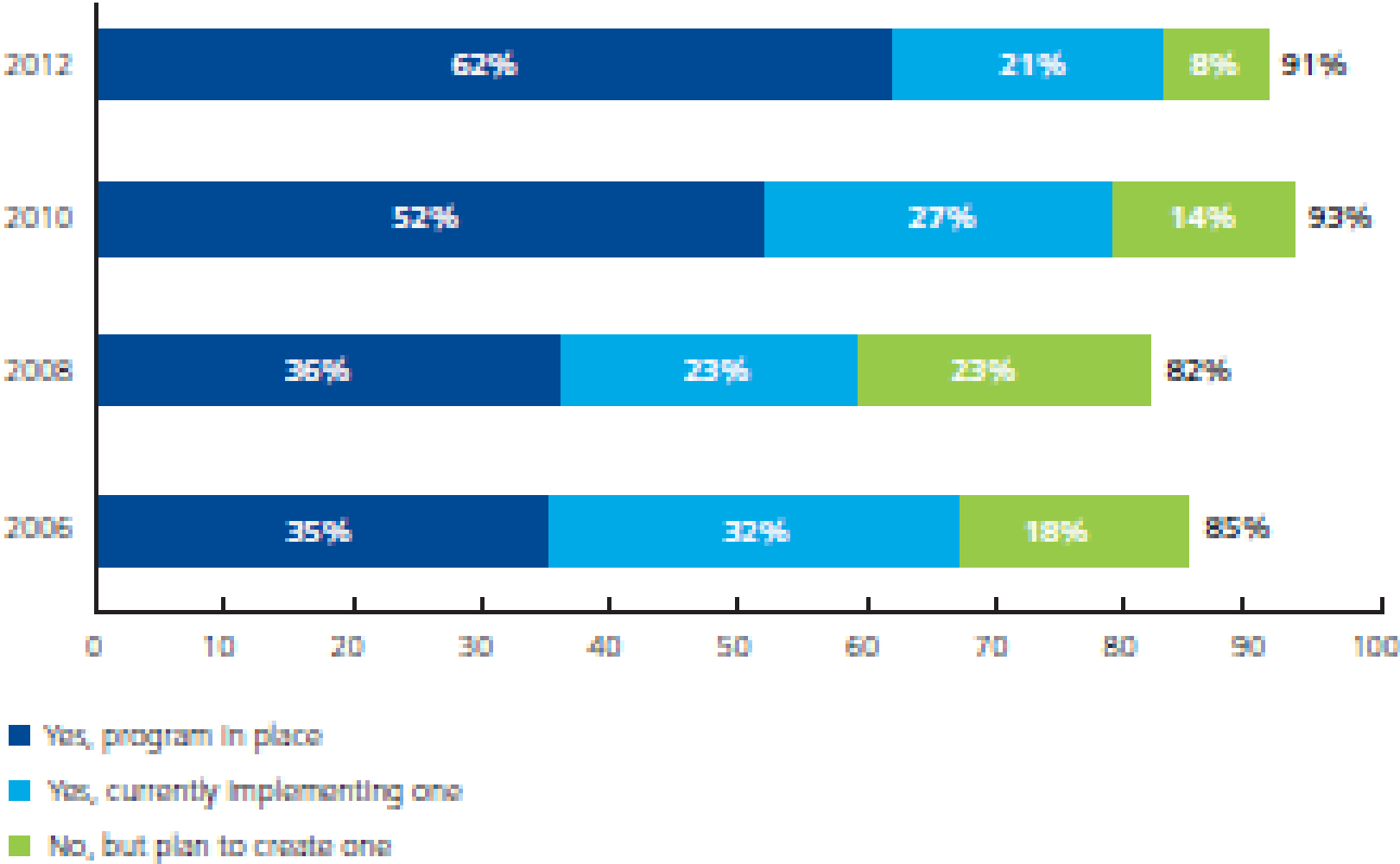
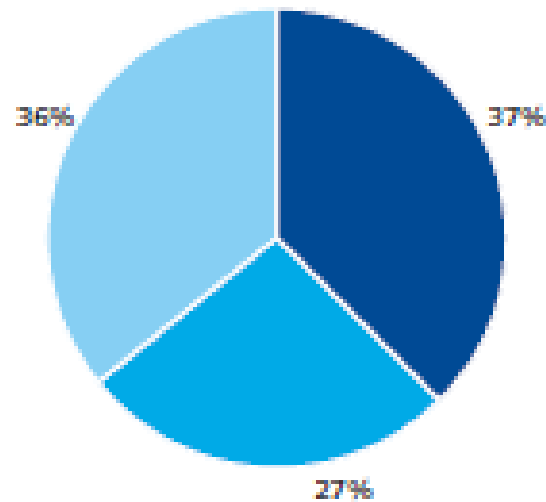


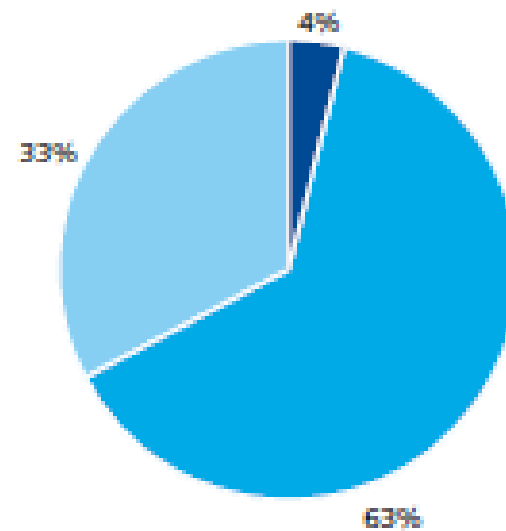
Figure 9. Which approach does your organization currently use or intend to use for Basel II on a consolidated basis for credit risk, market risk, and operational risk?

Credit risk



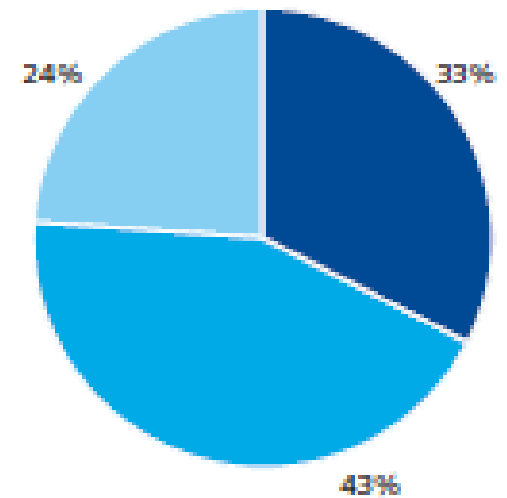
- Standardized
- Foundation IRB
- Advanced IRB

Market risk



- 1988 Risk Weight Rules
- Standardized Measurement Approach
- Internal Models Approach

Operational risk



- Basic Indicator
- Standardized/Alternative Standardized Approach
- Advanced Measurement Approaches

Figure 13. How effective do you think your organization is in managing each of the following type of risks?

